Patent Drafting: Disparities between Japanese and U.S. Practice

In a global patent world where parallel filings are sought for innovations in patent offices around the world, it continues to be a goal that one can draft a single patent disclosure as basis for global protection.

The goal remains elusive for a variety of issues, including questions as to whether the specification should include "problems" and "solutions" relating to the invention.

Japan Patent Office Guidance: Recently, the Japan Patent Office has published guidance which demonstrates the ongoing nature of this problem. *See* EXAMINATION GUIDELINES FOR PATENT AND UTILITY MODEL IN JAPAN (Provisional Translation)(Japan Patent Office Sept. 2015).

Disparities between U.S. and Japanese Practice: The writer's monograph, PATENT DRAFTING, has been updated to deal with the new Japanese guidance from its EXAMINATION GUIDELINES… *See* PATENT DRAFTING, §8[b][2], *Japanese Requirement to State "Problem" and "Solution"* (pp. 178-80); *see also id.,* § 6[c][5], *"Problems", "Objects" and "Advantages" for Japan Priority,* (pp. 145-49).

A copy of the latest version of PATENT DRAFTING is attached.

Regards,

Hal

PATENT DRAFTING

Crafting a first priority filing in a first-to-file world

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Case Law Last Updated September 5, 2015
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pre-publication version

for comments

prior to a final revision and

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SUMMARY OF CONTENTS

PREFACE

This book takes a front end view of the patent process: The vantage point is the preparation for the very *first* filing, which usually will be either a domestic provisional or an overseas Paris Convention application. This first filing, accomplished "today", will serve as a priority base for a second filing a year later as a regular (non-provisional) application. That second filing will be examined "tomorrow", perhaps in 2018 or later under a new Administration. Many changes may take place between "today" and "tomorrow", both in terms of the trend of the case law as well as examination policies of a new Under Secretary of Commerce. The biggest possible change could occur in the area of patent-eligibility under 35 USC § 101 based upon the view of the new Administration toward patents. Thus, the focus of the drafting process in changing areas is to provide a specification that has flexibility to introduce new claim forms "tomorrow" that will find support in the filing "today". *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

A Three-Fold Approach to Patent Drafting

Three critical features are focal points: First, the patent drafting framework, here, is that of a *first*, priority application in a first-to-file world; *second*, a *business* approach is taken to the drafting process which determines whether the exercise process takes one hour or hundreds of hours; and *third*, a holistic, simple application is the goal, to present a patent document easy to understand for both an examiner and the courts, one that optimizes protection and minimizes technical pitfalls.

(1) The First, Priority Application in a First-to-File World

This book is about drafting the first *priority* application for a first-to-file world "today" for an application that will be examined "tomorrow" under a new Administration. *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

Over fifty percent of *all* United States patents have at least one and often several priorities keyed to a provisional or Paris Convention overseas priority application, or are daughter continuation, continuation-in-part or divisional applications. A time efficient drafting of the priority application is vitally important when facing the realities of a first-to-file patent regime where the grace period can *never* be part of a prospective drafting strategy. It does no good to file a "perfect" application with all the bells and whistles suggested by the *Manual of Patent Examining Procedure* when that application is filed the day after a junior inventor has filed a focused application keyed to the *essential* statutory elements necessary for a solid patent:

The race to the Patent Office must be won; there is no silver medal for coming in second. Or, where an invention is presented at a scientific conference with the idea that an application would be filed in the near future under the "grace period" when a member of the audience makes a prior art divulgation of a *variant* of the invention that is outside the scope of the grace period.

(2) A Business Manager's Perspective of the Drafting Process

Priority patent drafting is approached through the lens of a *business manager* without which the filing process makes no sense. Management needs to take a hands on approach to directing the drafting effort. The entire effort may take a matter of an hour or so or up to several hundred hours, depending upon the technology and the state of the innovation: Once given a complete technical description and drawings for the preferred embodiment, the *business objectives* for many filings may call for spending no more than an hour or so for an already *completed* invention filed for defensive purposes. (The harm in spending several hundred unnecessary hours on an application goes beyond the expense of drafting the application but may be fatal to all patent rights if the extra expenditure of time means that a true first inventor is second-to-file in a first-to-file world.) At the other end of the spectrum where an upstream prototype in an unpredictable technology has been visualized but the ultimate commercial embodiment is yet to be created, the drafting process may take hundreds of hours to provide working and prophetic exemplary support to complement broad generic claims.

(3) A Simple, Holistic Approach to Patent Drafting

An overarching goal is the presentation of a holistic document that is *simple*, an easy to understand application and one that is easy to examine. The patent applicant *may* present twenty or fifty or sixty claims in an application as a matter of right. The patent applicant *may* cite seventy or eighty prior art citations to meet his duty of disclosure. The patent applicant *may* present a detailed *Background of the Invention* reciting a multitude of problems faced by the inventor which he has overcome through his new invention. This approach while open as a matter of *right* to any inventor is at the same time a prescription for failure, a road to a

protracted prosecution where the examiner is choked in a sea of too much information to digest within the limited time available for examination of each application.

Instead, each claim should be tied to a business objective: Many if not most applications should have five or ten or perhaps twelve or fifteen claims, and not the twenty or fifty of sixty claims. Where a prior art search has provided seventy or eighty citations, even if it is difficult to decide *which one* is the most pertinent, certainly a triage exercise can eliminate all but five or six prior art references as "cumulative": Eliminating most of the chaff makes the examiner's task much easier, which should be a goal of any presentation of a new application.

"Abstract" Software and "Natural" Product § 101 Patent-Eligibility

An extensive discussion is provided for how to draft a patent application where one element of the invention is an "abstract" software concept or a "natural" product. The discussion has many facets in chapters throughout the book, integrated in an introducing section § 1[b], *Technology-Specific Patent-Eligibility Challenges*.

Above all, it must be remembered that this book is focused on how to draft a patent application "today" which will be first examined "tomorrow" under new Executive Branch leadership where there could be major changes in examination that could refocus attention on Sections 102, 103 and 112 and away from patent-eligibility issues. *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

There is no "simple" way to deal with the patent-eligibility issues under 35 USC § 101 that plague software, pharmaceutical and biotechnology innovations. On the one hand, simple guidance on how to treat patent-eligibility issues short changes the need for a detailed exposition of the law which is clearly in a transitory state. On the other hand, a detailed exposition of the case law and how to create a test case to challenge the patent-eligibility case law is impossible reading for a person simply looking for a way to deal with the immediate realities that they do not have the ammunition for a test case.

To resolve this dilemma, a short section deals with the practicalities of life where a test case is not possible. *See* § 1[b], *Technology-Specific Patent-Eligibility Challenges.* On the other hand, an entire chapter deals with the *law* and how to draft a case "today", with proper support for various options for amendment when the case is examined "tomorrow" . *See* § 15, *Claiming Patent-Eligible Subject Matter*.

A Comparative Approach

The comparative material relating to Japanese patent law and practice is in large measure the result of the education given this writer by several persons including Tomatsu Aoyama, Shoichi Okuyama and Eiji Katayama. (It was Mr. Aoyama, together with Shoji Matsui and the late Professor Dr. Zentaro Kitagawa, who arranged the writer's early visits to Japan.) Thanks also are owed to Tetsu Tanabe for collaborations while the writer was a *Wissenschaftlicher Mitarbeiter* at the Max Planck Institute.

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A Thank you to Former Colleagues

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The first version of this book was written in early 2015 following the author's retirement from the Foley firm, starting on the writer's lanai in Pelican Bay topped off by editing on an Arctic Circle voyage between Akureyri and Murmansk.

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Naples, Florida
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PART (I): BUSINESS APPROACH TO PATENT DRAFTSMANSHIP

§ 1. Drafting should not be "Penny wise and pound foolish"

American corporate patent management responsible for oversight of its domestic and international patent procurement policies should consider one point: A greater emphasis should be placed on drafting the initial application as opposed to post-filing procurement. The need for an efficient, premium early filing is important under the current first-to-file system. The new system is quite unforgiving when it comes to drafting mistakes. Prospectively, one can no longer rely upon the *very* limited grace period (while the grace period does offer a still useful "Plan B" tool for the unexpected prior art divulgation of an invention where a patent application should have been filed, but wasn't, where the applicant should then *immediately* file to beat a third party's disclosure of a trivial variation that kills the grace period.)

On a broader scale, the first filing for many purposes is the "global" patent disclosure because if the American first filing does not meet the requirements of European and Asian laws priority may be lost: The inventor's post-filing publication may then bar some overseas patent rights.

All in all, the single most important patent drafting and prosecution event is the first filing. Many "sins" of bad practices at a later date of drafting and procurement are trivial compared to fatal defects that can be built into a patent family through errors in the first filing. The comparative patent law expert Paul Cole, speaking from the viewpoint of his native European country where first-to-

file has been at the center of patent ground rules for ages, notes that "[w]hat that experience teaches us [in the first-to-file world of Europe] is how desperately front-loaded the patent system is – if the right information and the right generalisations are not in the application as filed, the situation is likely to be irremediable and rights will be lost. That applies both at the provisional/first filing stage and at the utility/foreign filing stage. The [U.S. Patent and Trademark Office] may be relatively forgiving about added subject matter or priority, but the [European Patent Office] is not and the Chinese patent office seems to be modelling itself on the [European Patent Office]. The [United States] bean-counter driven trend towards low cost fixed price filing is an invitation to disaster because the cost of drafting the first filed or 12-month specification as a proportion of overall patenting costs is relatively low, but it is unwise economy at this initial stage that is likely to have the most serious consequences." Paul Cole, private communication, May 15, 2015.

With one exception this book may be seen as very "America centric" in that most of the chapters deal strictly with American patent practice. This is not to neglect European and Asian laws and practice, but rather a recognition of the difficulty of creating a clear understanding of *one* set of laws and practices: This is hard enough, without the complexity of dealing with the several laws of Europe and Asia.

The starting point for patent experts to reconsider filing strategies is the cold reality of first-to-file. This new system has multiple implications for patent drafting.

Because time is of the essence in filing a patent application in a first-to-file world, drafting the application requires a narrow focus on the critical issues necessary for an application.

Too much confusion has been generated in the area of patent drafting particularly in the past generation as many if not most prospective patent attorneys have focused their attention on passing the patent registration examination which, in turn, means that the focal point of study has been on the *Manual of Patent Examining Procedure.* There is a growing reality that the *Manual* is *not* the way to learn basic patent law and practice, yet the Patent Office directs the prospective registration candidate to study this nearly 3700 page document as the primary source of knowledge about patent practice. While there is much good in the *Manual* there are serious flaws in this document that has created a generation of new practitioners that are drafting patent applications that are much too complicated – both for applicants' interests as well as for the workload of the examining core.

"File a patent application!" Such an instruction is incomplete and only leads to confusion: The business objective of the applicant dictates the type of filing. If, for example, only defensive protection is needed for a specific embodiment, the entire drafting exercise can be focused upon the specification and, given a working example, one need spend no more than an hour or so drafting the application. At the other end of the spectrum is the "upstream" innovation in biotechnology prior to the creation of the "downstream" embodiments that will enter the marketplace. Creating claims as a prophecy of what will be created can take a considerable amount of time and effort both to visualize a genus and then to craft prophetic support for products not yet made.

Filing strategies are often industry-specific and should be taken into account. Currently, there is much concern within the academic community about the seeming destruction of its provisional filing model that is seemingly destroyed by a limited grace period, although as pointed out here, this need not necessarily be the case for most inventions from the academic community.

In keeping with the holistic theme that dominates this book, the individual pieces to the filing puzzle must be considered in a subordinate role to the big picture: The goal of patent drafting should be a simple, direct presentation of the invention. Simplicity has both a positive and a negative component. The *positive* component is the presentation beyond the claims of only what's important, which can and should be fit within the *Summary of the Invention.* The *negative* component is the array of elements should only obfuscate the invention and create a confused prosecution history, all of which should be *avoided* in drafting the application.

§ 1[a] Time to Draft the Very First Application: "Weeks?", "An Hour"?

The inventor provides the patent practitioner with a "cook book" example or "blue print" description of his invention containing a technical description of his best way of making and using his new "Widget", complete with any necessary technical drawings with reference numerals identifying the various features of his "Widget". How long should it take to draft a first application to protect the inventor's interests?

One hour? Weeks (or months)?

Each answer is correct for specific situations.

The "weeks" answer involves an unpredictable technology for a pioneer "upstream" discovery as in the case of a new family of biotechnology entities in an academic's laboratory, which is discussed more fully in § 1[a][1], *"Weeks": Offensive Coverage for Yet-to-be-Invented Products*. The academic has discovered a brand new core for a family of pharmaceutically interesting molecules, but so far has made and tested only one – a prototype entity that is basis for continuing research to make literally hundreds of variants, all with the goal of finding one with both the best efficacy *and* without a toxicity profile that would make it difficult or impossible for clinical development. This is the *Ariad* situation where it may take weeks or months to make or even prophetically describe representative examples for the entire family of biotechnology entities having the inventor's family of molecules. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). *See* §7[f], *Generic Support for an "Unpredictable" Ariad Invention* (discussing the sequential filing of a first provisional application with limited exemplary support complemented by a second provisional application containing representative exemplary support).

Here, the objective is not defensive but rather offensive, to gain an exclusive right to the entire family of biotechnology entities. But, the inventor will not be able to gain a broad claim covering the entire family because the single example will not establish "possession" of the family under the *Ariad* line of case law.

As a practical matter, an early *provisional* application may be filed with a proper definition of the family of biotechnology entities as "claim 1" backed up by the single example. The priority date will provide the best guarantee to block a junior inventor from gaining a claim that would dominate the entire family. But, *absolute secrecy* must then be continued until a second – or even third – provisional application is filed which contains additional examples which are

based on actual working examples, detailed prophetic biotechnology – or both. Ideally, the secrecy would be maintained for the full eighteen months from the date of the first priority filing so that further subgeneric and specific coverage can be obtained without any patent-defeating effect through premature publication.

The opposite end of the spectrum – the "one hour" application – is the situation where a "Widget" is about to be commercially launched; there is no likelihood that this "Widget" will ever be modified to a different commercial form; and the *only* business interest is defensive. § 1[a][2], *"One Hour": Defensive Coverage for an Existing Embodiment.*

Here, indeed, it should take no more than an hour or so to prepare and file the patent application, once given the disclosure of an enabled embodiment from the inventor. Essentially *any* claim can be provided to complement the specification which may have nothing more than the description of the enabled embodiment. The goal under the new patent law is simply to obtain the earliest filing date for the enabled embodiment which, upon automatic publication 18 months from the priority date, will have a patent-defeating effect to defeat novelty and nonobviousness as of that priority date.

Prior to the *Leahy Smith America Invents Act* it was important to have a *claim* that could be found allowable to cover the "Widget" because a third party with a junior filing date could seek to establish priority before the applicant's filing date, but that is no longer possible. Furthermore, to the extent that the third party would seek to overcome the inventor's filing date through an argument of derivation, the inventor has the insurance policy of an *inter partes* proceeding to establish anticipation as part of a trial at the Patent Office under Post Grant Review (PGR).

§ 1[a][1] "Weeks": Offensive Coverage for Yet-to-be-Invented Products

On the one hand the most difficult challenge of all involves drafting a patent application for *offensive* protection to cover as yet undiscovered "downstream" products in chemical or biotechnology research at a time when the research is still at an "upstream" stage where there may be one or two prototype products that *have* been created but undoubtedly the best, commercial products have yet to be created. While the legal issues in the cases are different, the classic factual setting representing the "upstream"/"downstream" situation *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 202 (2005), where Integra invented a genus of compounds at the "upstream" stage where specific embodiments at the "downstream" stage were invented by Merck's partner, the Scripps Clinic.

Classically, many of the "upstream"/"downstream" situations arise keyed to the "upstream" research of academic institutions such as the work of the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and Harvard College as part of *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc), where Eli Lilly then invented the specific "downstream" products for commercial marketing. Lilly, of course, had its own *specific* patent position on its newly discovered molecule, but the Ariad patentees had a generic claim dominating the entire field based upon limited exemplary support. Here, the Ariad patentees expected royalties from Eli Lilly for its product that fell squarely within its generic coverage: But, the Ariad patentees did not have sufficient representative exemplary support to demonstrate "possession" of the family. The situation of the *Ariad* case will only become more problematic under the *Leahy Smith America Invents Act* because if the pioneer inventor in the situation of the patentees in the *Ariad* case somehow do slip through the examination to gain a patent, a future "Eli Lilly" will be able to

challenge validity through a Post Grant Review (PGR) that is now available for patents filed after the effective date of the *Leahy Smith America Invents Act.*

For offensive protection based on rudimentary test results of prototype products the inventor must envision an often broad generic definition of products, many (or most of which) have not yet been made. Great skill and experience is required to lay out the proper generic claim. Even greater skill is required to create the prophetic examples necessary to support the generic definition to show "possession" of that generic invention under the *Ariad* case.

§ 1[a][2] "One Hour": Defensive Coverage for an Existing Embodiment

At the other end of the spectrum remote from the pioneer "upstream" invention one encounters the situation that the drafting task is only to provide *defensive* coverage to protect a *specific* existing product: The sole goal of the patent application is to provide coverage to block a third party from obtaining a claim that will dominate this *specific* existing product.

Here, filing "immediately" once there is a "cook book" example or "blue print" disclosure of the invention should be the goal; this example forms the heart of the detailed disclosure.

A claim that "fingerprints" the entire identity of the specific example is all that is needed to complement this example. (To be sure, this is a claim like that in the *Pennwalt* case which is rightly criticized for allowing an easy design around the invention to avoid infringement. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987)(en banc). But, if *defensive* protection is all that is needed, a *Pennwalt* claim is perfectly fine.)

If the patent practitioner has been provided with the "cook book" or "blue print" disclosure of the preferred embodiment, it should not take much time at all to put together a proper application in a matter of a couple of hours, plus whatever scrivener time is involved in putting together the "cook book" or "blue print" disclosure.

Whether the claim or claims pass muster in this case is largely irrelevant because the patent-defeating right is created by the automatic publication of the application 18 months from the priority filing date. Absent any derivation issue, any subsequently filed third party patent application with claims that read on either the example or is to novel subject matter obvious over the example will be barred by the published disclosure.

§ 1[a][3] The Many Shades of Gray, Mixed Objectives

Most cases fall somewhere between the two examples.

For example, a defensive application may also desirably provide offensive protection to block a third party from practicing the invention. While a *Pennwalt* claim is desirable from a *defensive* point of view, the lesson of *Pennwalt* is to provide generic coverage for a combination invention where only the *essential elements* to establish patentability will be included in "claim 1."

Another typical scenario is that while the applicant wants defensive coverage to block third party domination of his *current* embodiment, the applicant would also like to block third party domination of *variants* to permit changes in the practice of the technology. For example, a defensive patent may be obtained

for a new compound that will block domination of that compound, but it may not dominate variations that the applicant may wish to consider at a future date.

Here, just as a "checkerboard" has many squares, envision the field of the invention as a checkerboard where the current embodiment occupies just one square. Here, a broad defensive situation should involve filling in the checkerboard with prophetic examples. Another challenge is that new uses may be discovered for a defensive disclosure of a new product. If a competitor patents the combination of the new product with a new use, then the applicant will be blocked from commercialization of his new product with the new use.

1[a][4] Priority Document for Foreign Protection

Is this invention to be the subject of patent protection in Asia and Europe?

If the answer is yes, the business objectives must be modified so that the earliest possible priority date can be achieved. This may mean filing an "immediate" provisional application where an enabled embodiment is included and *some* claims are provided, coupled with continued secrecy of the invention and then, as soon as possible, a *second* provisional application that contains the full range of disclosure needed for foreign protection.

1[a][5] Clear Written Understanding of the Business Objectives

Where there is any ambiguity in the applicant's instructions as to business goals, it is best that the practitioner discuss this with the applicant to create a firm understanding of the business objectives. A written record should be made of this understanding so that this will become a permanent part of the prosecution file.

§ 1[b] Technology-Specific Patent-Eligibility Challenges

"Inventive" applications of software and biotechnology innovations as well as diagnostic methods have come under special scrutiny under 35 USC § 101 through a series of cases denying patent-eligibility starting with *Bilski* v. *Kappos*, 561 U.S. 593 (2010)(software), and continuing with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(diagnostic method); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107, 2116 (2013)(DNA); and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software). The current section deals with the pragmatic realities of dealing with the Patent Office interpretation of these cases where the goal is to gain a patent of any kind without an appeal.

For a first filing "today", however, there may be some hope that when a new President in 2017 names a new Under Secretary of Commerce to head the Patent Office that the new Administration will take a more favorable view to patent-eligibility more in line with the historic case law as outlined in § 15, *"Inventive" Patent-Eligible Subject Matter*. *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce). There is, at this writing, no expectation that a particular candidate or party will prevail in the November 2016 election, much less who the new Under Secretary will be nor what policies may be taken. In any event, for a first filing "today", the application will be *examined* under a new Administration: It is important, therefore, that any application drafted for a first filing "today" should focus on the realities of the case law and not the current Patent Office guidance which deviates from such case law.

To be sure, it must be recognized that even if an invention is patent-*eligible* this does not mean that it is *patentable* under the statutory standard of nonobviousness under 35 USC § 103. Thus, the title of the chapter 15 directly states that the quest is to define "inventive" patent-eligible subject matter. *Id.*

§ 1[b][1] Clear Definition of an "Inventive" Feature

Patent-eligibility under 35 USC § 101 for the "abstract" inventions involved with software and the "natural" products of biotechnology is in a state of flux. The goal of this discussion is to provide detailed strategies that may be successful at the level of the Patent Trial and Appeal Board (or the Federal Circuit).

A variety of approaches must be taken to be successful. In the first instance, claims should be drafted in a way that places the "abstract" concept or "natural" product as one of the elements in a combination claim which preferably is part of an overall industrial process or composition. The application needs to be crafted to define all elements of the claim as critical to the *combination* invention so that the claimed invention *as a whole* will be examined. To top this all off, the practitioner will need to master a series of historic Supreme Court case law dating back to the nineteenth century to put into proper perspective the handful of recent cases. And, above all, inventions that are truly meritorious will have the best chance of success.

A new filing regime is required for software and biotechnology innovations now under siege under Section 101 patent-eligibility considerations: First filings in areas impacted by Section 101 issues should now focus upon the presentation of combination claims that are supported by argumentation in the specification or preliminary amendment that explain in detail why the claimed *combination* is

nonobvious under Section 103, and, hence, possesses the "inventive concept" needed for patent-eligibility under *Chakrabarty* and *Diehr*. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)(oil eating novel microorganisms); and *Diamond v. Diehr*, 450 U.S. 175 (1981)(method for curing rubber).

Complementing this approach the combination claims should include (a) an at first blush "conventional" element *or elements* critically defined as part of the claimed invention; (b) *plural* physical elements in seeming violation of the "all elements" rule to bolster patent-eligibility (while preserving the right for continuing application that may subsequently round out protection); and (c) are *Diehr*-modelled to focus upon a physical process such as molding rubber where the Section 101 element is only one feature of the physical process.

In terms of argumentation to gain allowance of claims it is important to establish an "inventive" feature for the claimed subject matter. A detailed discussion below explains why an "inventive" feature should be considered to be merely a pre-1952 English usage that translates into nonobviousness. It is vital that the nonobvious feature of the *combination* invention be stressed.

Missing in all of the discussions, here, are the "Hirshfeld Guidance" and other guidelines from the Director or the Commissioner for Patents. (Currently, the "Hirshfeld Guidance" is in the process of being replaced by what is here styled as the "Lee Guidance". *See* § 1[b][6], *"Lee Guidance" Superseding the "Hirshfeld Guidance*"). The audience for the strategies set forth in this book as to "abstract" and "natural product" inventions is the Patent Trial and Appeal Board and *not* the examining corps that is bound by the "Hirshfeld Guidance". *See* § 1[b][4], *Bypassing the "Hirshfeld Guidance"*.

By crafting carefully tailored and specific claims and arguments where the equities favor the applicant, it may be possible to prevail. In the end, success or failure will to a great extent be largely dependent upon the equities. Where all the applicant has done is to add a software solution to a business method and the combination is obvious, whether the rejection is a "try it" denial under *Mayo* or *Alice* or an obviousness denial under *KSR* the form of the rejection will not trump the substance. *KSR International Co. v. Teleflex Inc*., 550 U.S. 398 (2007). But, where there is a true breakthrough as in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(prenatal paternal generic screening invention).

The road to a patentable invention keyed to an "abstract" concept or "natural" product is to craft a combination claim that clearly associates that concept or product as part of a combination claim that is "inventive". From a standpoint of both establishing the equities to favor the applicant and also meet the requirement that the subject matter is "inventive", the far more important task is to establish the nonobviousness of either a subcombination or the entire combination as claimed. *See* § 15[a], *Patent Eligibility and Patentability Conflated.*

To understand what is meant by "inventive" subject matter, it is important to understand that the current Supreme Court case law is freshly minted within the current lifetime of senior practitioners: It is *not* a matter of a matter of "*stare decisis* going back 150 years[.]" *Prometheus Laboratories, Inc. v. Mayo Collaborative Serv.*, 628 F.3d 1347, 1353 (Fed. Cir. 2010)(Lourie, J.)(citing *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174-75 (1853)), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012). The seminal case that is cited deals neither with an "abstract"

concept or a "natural" element but instead involves technology to make a *pipe* where the claims were not properly cast to cover the inventive feature. *See* § 15[d][1], *Le Roy v. Tatham: "[S]tare decisis going back 150 years."* To be sure, even earlier English case law is cited for the proposition that there is an exception to patent-eligibility, mythology exposed by a significant Federal Circuit scholar. *Id.*, quoting *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(Linn, J., concurring), citing Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015).

§ 1[b][2] Claiming a *Diehr*-Like Physical Process

Beyond defining "inventive" – or nonobvious – subject matter it is also important to package the inventive subject matter in a combination claim that has clear physical limitations. This subject is considered in detail at § 15[c][1], *"Conventional" Element vs. Combination "As a Whole".* Once an "inventive" feature is identified it must be properly packaged in a combination claim. § 12[b][1], *"Inventive" Feature in a Combination Claim.*
Thus, a claim must be presented which is to an otherwise conventional process where an algorithm or biological product is one *element* of that combination. Thus, in the *Diehr* case the applicant was successful in sustaining patent-eligibility where the claim was to a method of curing rubber the mathematical steps of an equation were just one element of the claim. *See* § 15[b][4], *Diehr vs. a Simplistic "Apply it" Claim Approach* (discussing the approach in *Diamond v. Diehr*, 450 U.S. 175, 188 (1981)).

The *Diehr* claim is the antithesis of an "apply it" claim where the body of the claim is focused upon an algorithm followed by a generically stated, conventional step that applies the algorithm to a process. *Id.* (quoting *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347, __ (2014), quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012)("*Mayo* made clear that transformation [of an abstract idea] into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' ")).

§ 1[b][3] Purposeful Violation of the "All Elements" Rule

A "Diehr claim" should be presented that is modeled after the claims in *Diehr* which are cast as a method for curing rubber. *See* § 15[b][4], *Diehr vs. a Simplistic "Apply it" Claim Approach.*

In traditional technologies, generic "claim 1" in any application should, as a general rule, recite the "minimum elements" necessary to establish nonobviousness of an invention. See § 13, *"All Elements" Claim Drafting Rule* (discussing the practice under *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987) (en banc)). But, in the case of a claim on the borderline of Supreme Court patent-eligibility standards, it is important to include at least one physical limitation as a prominent feature of the claims, and to include as many physical elements as possible *which are necessary for the commercial application of the invention.*

In some instances the *commercial* embodiment may have, say, five physical steps and one algorithm-keyed step, but it is important for generic protection to have a much broader claim without all the physical steps. Here, one solution is to

have multiple sets of claims with one to the six step commercial embodiment and others claims to the minimum elements needed for nonobviousness.

When a restriction requirement is made, the "six steps" claim can be elected that will clearly stress the patent-eligibility of the invention *as a whole* as being more than directed to the algorithm step.

(Later, a continuing or divisional application can be filed to the claims with the minimal number of steps.)

§ 1[b][4] Bypassing the "Hirshfeld Guidance"

For *drafting* a patent application, it is important to stay focused upon the Supreme Court and Federal Circuit case law to craft claims to meet the judicial standards set by these tribunals. At best minimal consideration should be given *at the drafting stage* to the so-called the so-called "Hirshfeld Guidance" issued in the wake of *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014), will have long been superseded by Federal Circuit case law. *See Instructions to the Patent Examining Corps under Deputy Under Secretary of Commerce Michelle K. Lee* authored by Andrew Hirshfeld, Deputy Commissioner for Patent Examination Policy, *Preliminary Examination Instructions in view of the Supreme Court Decision in Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*, June 25, 2014. It can be imagined that every examiner in the relevant arts has electronic access to a pet form paragraph keyed to the notorious Hirshfeld Guidance.

It is understandable as a practical matter that a disposals-driven examining corps will take the easy and fastest way to examine complex technological and legal issues by simply rejecting claims under 35 USC § 101 on the basis of the Hirshfeld Guidance.

The best approach for a truly meritorious invention is to present claims according to the outline given in this section coupled with legal arguments that follow *Diehr* and emphasize the invention as a whole where, for example, an algorithm or natural product is only one element of that invention as a whole.

It may well be that an Examiner will answer with an electronically generated Hirshfeld Guidance-keyed rejection, but then if an appeal is filed that *could* be brought all the way to the Federal Circuit, the chances are very good that the claims will be allowed on the basis of the brief without even reaching the Patent Trial and Appeal Board.

(Experience teaches that test cases brought for consideration at the Board with strong legal arguments, excellent equities and an unemotional flat tone have often been short-circuited and never reached the Board: They have resulted in a correct decision being reached by the Examiner, *without* going forward with the appeal. Beyond the fact that the Examiner is doing his or her job by allowing the case, for the segment of the examining corps that is looking for the easy way to a disposal that segment will find a simple allowance a far better choice than fighting a difficult and possibly losing legal battle at the PTAB.)

§ 1[b][5] Value of the "Hirshfeld Guidance" during Examination

By the time an application drafted "today" is up for a first action on the merits by the Examiner, there will have been an elapsed time interval of anywhere from 18 months to three years or more. In that interval, the so-called "Hirshfeld Guidance" will have been supplanted by a series of Federal Circuit cases that will not depend on nor necessarily follow the Patent Office policy statement. Indeed, there is now pending a revision of the Hirshfeld Guidance. The new guidance is discussed below at § 1[b][6], j*"Lee Guidance" Superseding the "Hirshfeld Guidance***"**)

Even if the Hirshfeld Guidance had been the most carefully thought out work product of the legal minds of the Solicitor's Office and the Patent Trial and Appeal Board, it makes little sense to teach how to meet the standards of the Hirshfeld Guidance when there is no precedential value provided by this effort of the administrative leadership of the Patent Office: The real challenge is to provide a well-drafted patent application that *distinguishes Alice v. CLS Bank* and the preceding several Supreme Court rulings against patent-eligibility.

The Hirshfeld Guidance, however, is only deserving of the respect that a document produced "overnight", without reflection, deserves. (The Hirshfeld Guidance was only figuratively given "overnight", while in fact it was issued six (6) days after the Supreme Court decision.)

Does the Hirshfeld Guidance manifest careful and thoughtful reflection and input from the patent community – both inside and outside the Patent Office? The "overnight" analysis speaks for itself. The premature birth of the Hirshfeld Guidance also manifests the absence of significant participation by either the Solicitor's Office or the Patent Trial and Appeals Board.

The Hirshfeld Guidance was issued in sharp contrast to Patent Office regulations published in the *Federal Register* that generally go through a long period of gestation. Such regulations first are introduced as a carefully thought out and detailed *proposal* published in the *Federal Register.* Following a comment period that give the public an opportunity to advise on possible modifications, *then* a final regulation is published in the *Federal Register*. The final notice is indeed entitled to a great deal of respect.

The premature birth of the Hirshfeld Guidance also manifests the at most minimal significant participation by either the Solicitor's Office or the Patent Trial and Appeals Board.

§ 1[b][6] "Lee Guidance" Superseding the "Hirshfeld Guidance"

The "Hirshfeld Guidance" is in a state of flux and is expected to be replaced by the "Lee Guidance". In part based upon his contributions to this guidance, on July 30, 2015, the author of the Hirshfeld Guidance was promoted to the position of Commissioner for Patents for a term that will run into the year 2020.

The "Lee Guidance", here, refers to Under Secretary Lee's published "update" to it's the original "Hirshfeld Guidance", the *2014 Interim Guidance on Subject Matter Eligibility,* available at http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0. The Under Secretary asks for comments concerning the updated guidance which will be accepted through October 28, 2015.

Because a picture is sometimes worth a thousand words, excerpts from a Lee Guidance "workshop" example are provided in the pages following this section. The Lee Guidance has several shortcomings:

First of all, the Lee Guidance does not have the weight of statutory or case law authority in support of what the guidance says. This creates a truly lose-lose scenario: If on the one hand the Lee Guidance sets forth too liberal a standard of patent-eligibility beyond the Supreme Court case law, grant of a patent keyed to such liberality can be immediately challenged after grant in a Post-Grant Review. Thus, for any application filed "today", the new Post Grant Review procedure will be applicable where any third party can challenge a patent for patent-eligibility at the Patent Trial and Appeal Board. Conversely, if the standard is too difficult – going beyond the case law – it will be difficult to convince an Examiner based upon the case law because of the heavy emphasis the Patent Office is placing on its own guidelines.

Secondly, the guidance provides a mechanism for analysis that radically departs from a proper analysis of an invention. As seen from § I of the "Workshop" example the Examiner determines patent-eligibility not by reference to what the claim says, but the Examiner's analysis of what the invention is governs with the subject matter eligibility determination. Thus, the Examiner is instructed as the very first stage of the analysis not to focus on the claim but rather

the Examiner's own "brief description" of the invention which "should not merely reproduce the claim."

Thirdly, the "inventive" feature of a claim surely refers to whether an element or the claimed invention as a whole is nonobvious, yet there is nothing in the guidance that suggests that a nonobviousness examination should be conducted. If the invention is nonobvious, then the Patent Office should consider that the invention *does* have "inventiveness" or an "inventive" step.

The guidance appears directed to giving an examiner a shortcut to *avoid* a patentability search and examination simply by a nonstatutory analysis of the claim and the examiner's prior art-free determination whether the claimed subject matter is "inventive". Examiners should be instructed in the first instance to do a complete search and examination for traditional patentability issues and *then*, if necessary, move on to Section 101 patent-eligibility.

It would be expected that where an applicant submits an Information Disclosure Statement (IDS) and the Examiner cites no closer prior art, to the extent that the IDS establishes patentable novelty, the argument can and will be made by the inventor to the Patent Trial and Appeal Board that, as a nonobvious invention, the claimed subject matter is *a fortiori* patent-eligible.

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE"

PATENT OFFICE "WORKSHEET" TO ANALYZE WHETHER A CLAIM IS DIRECTED TO PATENT-ELIGIBLE SUBJECT MATTER

excerpted from
http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0 (last visited July 31, 2015)

SUBJECT MATTER ELIGIBILITY WORKSHEET:

For use in abstract idea workshop

This worksheet can be used to assist in analyzing a claim for "Subject Matter Eligibility" (SME) under 35 U.S.C. 101 for any judicial exception (law of nature, natural phenomenon, or abstract idea) in accordance with the 2014 Interim Eligibility Guidance. As every claim must be examined individually based on the particular elements recited therein, a separate worksheet should be used to analyze each claim.

For purposes of simplicity in this workshop, the questions below only refer to *abstract ideas* and will be used to walk through several of the abstract ideas examples published on the website. (A blank generic worksheet is available on the training website.) It is suggested that the worksheet be used with the *2014 Interim Eligibility Guidance Quick Reference Sheet*, which includes an overview of the analysis, along with the flowchart and form paragraphs referenced herein.

Worksheet Summary: Section I is designed to address the first activity in examination, which is to determine what applicant invented and to construe the claim in accordance with its broadest reasonable interpretation (BRI). Next, referring to the eligibility flowchart reproduced in the *Quick Reference Sheet*, Section II addresses *Step 1* regarding the four statutory categories of invention. Section III addresses *Step 2A* by determining whether the claim is directed to an abstract idea. Section IV addresses *Step 2B* by identifying additional elements to determine if the claim amounts to significantly more than an abstract idea.

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

Application/Example No. and claim: Example 1, claim 2

I. What did applicant invent?

Review the disclosure to identify what applicant considers as the invention. (MPEP 2103(I))

Applicant invented:

An extraction method that isolates and removes malicious code from electronic messages.

This can be a brief description and should not merely reproduce the claim. The take away is that the invention focuses on scanning and cleaning electronic communications.

Establish the broadest reasonable interpretation (BRI) of the claim.

II. Does the claimed invention fall within one of the four statutory categories of invention (process, machine, manufacture or composition of matter) (Step 1)?

Choose A or B:

A. Yes, the claimed invention is a a non-transitory computer-readable medium comprising instructions stored thereon, which is a manufacture.

Although this is a product claim, it is not automatically eligible and needs further analysis to ensure that the claim is not directed to an abstract idea without significantly more.

Continue with the SME analysis.

B. No, the claimed invention is not one of the four statutory categories. Make a rejection of the claim as being drawn to non-statutory subject matter. *Use Form Paragraphs 7.05 and 7.05.01 available in Custom OACs.*

If the claim could be amended to fall within one of the statutory categories, it is recommended to **continue with the SME analysis** under that assumption. Make the assumption clear in the record if a rejection is ultimately made under *Step 2*, and consider suggesting a potential amendment to applicant that would result in the claim being drawn to a statutory category.

If no amendment is possible, **conclude the SME analysis** and continue with examination under each of the other patentability requirements.

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

III. Is the claim directed to an abstract idea (Step 2A)?

Courts have found certain concepts to be "abstract ideas", for example fundamental economic practices, certain methods of organizing human activity, ideas themselves (standing alone), or mathematical relationships/formulae. Assistance in identifying such abstract ideas can be obtained by referring to the case law chart available on the website and the court case discussions in the 2014 Interim Eligibility Guidance. A claim is "directed" to an abstract idea when the abstract idea is recited (*i.e.*, **set forth** or **described**) in the claim.

Choose A, B, or C:

The claim is eligible.

A. No, the claim does not recite a concept that is similar to those found by the courts to be abstract. **Conclude SME analysis** and continue with examination under each of the other patentability requirements. If needed, the record can be clarified by providing remarks in the Office action regarding interpretation of the claim (*for example*: the broadest reasonable interpretation of the claim is not directed to an abstract idea.)

The claimed invention relates to software technology for isolation and extraction of malicious code contained in an electronic communication. The executable instructions of physically isolating a received communication on a memory sector and extracting malicious code from that communication to create a sanitized communication in a new data file does not describe an abstract concept. This process is not similar to any concepts found by the courts to be abstract. The claim is eligible.

An explanation of why t claim is eligible is not necessary in the Offic action unless there would question as to the reasor such that the record wo benefit from clarificati

B. Yes, but the streamlined analysis is appropriate as the eligibility is self-evident, and a full eligibility analysis is not needed. Applicant's claimed invention, explained in Section I above, is not focused on the abstract idea, and the claim clearly does not attempt to tie up an abstract idea such that others cannot practice it. (Refer to the February 2015 Training Slides for information and examples of a streamlined analysis.) **Conclude SME analysis** and continue with examination under each of the other patentability requirements.

C. Yes, identify the limitation(s) in the claim that recite(s) the abstract idea and explain why the recited subject matter is an abstract idea. After identifying the abstract idea, **continue with SME analysis.**

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

SUBJECT MATTER ELIGIBILITY WORKSHEET:
For use in abstract idea workshop

The limitation(s) in the claim that set(s) forth or describe(s) the abstract idea is (are):

_____

_____

_____

The reason(s) that the limitation(s) are considered an abstract idea is (are):

_____

_____

IV. Does the claim as a whole amount to significantly more than the abstract idea (Step 2B)?

A. Are there any additional elements (features/limitations/step) recited in the claim beyond the abstract idea identified above?

Choose 1 or 2:

1. No, there are no other elements in the claim in addition to the abstract idea. **Conclude SME analysis** by making a § 101 rejection and continue with examination under each of the other patentability requirements. *Use Form Paragraphs 7.05 and 7.05.015 available in Custom OACs.*

   Are there elements in the disclosure that could be added to the claim that may make it eligible? Identify those elements and consider suggesting them to applicant:

   _____

   _____

2. Yes, the claim elements (features/limitations/steps) in addition to the abstract idea are:

   _____

   _____

   _____

   Continue with the SME analysis.

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

B. Yes, but the streamlined analysis is appropriate as the eligibility is self-evident, and a full eligibility analysis is not needed. Applicant's claimed invention, explained in Section I above, is not focused on the abstract idea, and the claim clearly does not attempt to tie up an abstract idea such that others cannot practice it. (Refer to the February 2015 Training Slides for information and examples of a streamlined analysis.) Conclude SME analysis and continue with examination under each of the other patentability requirements.

C. Yes, identify the limitation(s) in the claim that recite(s) the abstract idea and explain why the recited subject matter is an abstract idea. After identifying the abstract idea, continue with SME analysis.

The limitation(s) in the claim that set(s) forth or describe(s) the abstract idea is (are):

_____

_____

_____

The reason(s) that the limitation(s) are considered an abstract idea is (are):

_____

_____

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

IV. Does the claim as a whole amount to significantly more than the abstract idea (Step 2B)?

A. Are there any additional elements (features/limitations/step) recited in the claim beyond the abstract idea identified above?

Choose 1 or 2:

1. No, there are no other elements in the claim in addition to the abstract idea. Conclude SME analysis by making a § 101 rejection and continue with examination under each of the other patentability requirements. *Use Form Paragraphs 7.05 and 7.05.015 available in Custom OACs.*

   Are there elements in the disclosure that could be added to the claim that may make it eligible? Identify those elements and consider suggesting them to applicant:

   _____

   _____

2. Yes, the claim elements (features/limitations/steps) in addition to the abstract idea are:

   _____

   _____

   _____

   Continue with the SME analysis.

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

B. Evaluate the significance of the additional elements. Identifying additional elements and evaluating their significance involves the search for an "inventive concept" in the claim. It can be helpful to keep in mind what applicant invented (identified in Section I above) and how that relates to the additional elements to evaluate their significance.

Consider all of the identified additional elements individually and in combination to determine whether the claim as a whole amounts to significantly more than the abstract

idea identified above. Reasons supporting the significance of the additional elements can include one or more of the following:

- improves another technology or technical field
- improves the functioning of a computer itself
- applies the abstract idea with, or by use of, a particular machine
  - *not* a generic computer performing generic computer functions
  - *not* adding the words "apply it" or words equivalent to "apply the abstract idea"
  - *not* mere instructions to implement an abstract idea on a computer
- effects a transformation or reduction of a particular article to a different state or thing
- adds a specific limitation other than what is well-understood, routine and conventional in the field
  - *not* appending well-understood, routine, and conventional activities previously known to the industry, specified at a high level of generality
  - *not* a generic computer performing generic computer functions
- adds unconventional steps that confine the claim to a particular useful application
  - *not* adding insignificant extrasolution activity, such as mere data gathering
- adds meaningful limitations that amount to more than generally linking the use of the abstract idea to a particular technological environment

THE "LEE GUIDANCE", "WORKSHEET EXAMPLE" (*con'd*)

Complete (1) or (2) below:

1. Yes, the additional elements, taken individually or as a combination, result in the claim amounting to significantly more than the abstract idea because

_____

_____

_____

If any elements, individually or as a combination, amount to the claim reciting significantly more than the abstract idea, **conclude SME analysis** and continue with examination under each of the other patentability requirements. If needed, the record can be clarified by providing remarks in the Office action regarding interpretation of the claim (*for example*: the claim recites the abstract idea of "x", but amounts to significantly more than the idea itself with the additional element "y" because "abc".)

2. No, the additional elements, taken individually and as a combination, do not result in the claim amounting to significantly more than the abstract idea because

_____

_____

_____

If no elements, taken individually and as a combination, amount to the claim reciting significantly more than the abstract idea, **conclude the SME analysis** by making a § 101 rejection and continue with examination under each of the other patentability requirements. *Use Form Paragraphs 7.05 and 7.05.015 available in Custom OACs.*

Are there elements in the disclosure that could be added to the claim that may make it eligible? Identify those elements and consider suggesting them to applicant:

_____

_____

§ 1[b][7] New Approach in a New Administration in 2017

This book focuses upon drafting the first, priority application "today" which will receive a first action on the merits two or more years from now, at a time when there is a new President and a new Under Secretary of Commerce in charge of running the Patent Office. No matter which party wins the election, it is difficult to think that the new leadership of the Patent Office could be any less friendly toward patent applicants in the area of "abstract" technology under 35 USC § 101. *See* § 1[b][7], *The New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

There are many ways that a new Administration could take a fresh approach to examination of "abstract" innovations. Perhaps the most important approach would be to treat "abstract" innovations in the same manner as any other subject matter area, to provide a complete examination on the merits of every case, including an examination for novelty, nonobviousness and formalities. 35 USC §§ 102, 103, 112. Perhaps the examiner should be required in the first instance to examine *only* under these standard statutory criteria and *not* in the first instance consider patent-eligibility under 35 USC § 101. After all, if the invention is "obvious", then there is no "inventive step" to consider under Section 101. And, if there *is* a nonobvious invention, then there *is* an "inventive step" present.

To be sure, there may be skeptics who think that there is some gray area where an invention may be nonobvious but still should be subject to rejection under 35 USC § 101. For such a case, the Patent Office should detail and embed I the relevant Technology Centers several Administrative Patent Judges who would take over an application with such an issue: They would then decide whether there

is in the first instance merit in a further rejection, and, if so, promptly push the case up the appellate ladder acting as Examiners, followed by an expedited hearing at the Patent Trial and Appeal Board.

It is recognized that the Supreme Court in its evaluation of patent-eligibility declined the Government's suggestion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), to focus a validity determination on patentability issues under 35 USC §§ 102, 103, 112:

[T]he Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as *Amicus Curiae.* The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. §102, that it not be 'obvious in light of prior art,' §103, and that it be 'full[y], clear[ly], concise[ly], and exact[ly]' described, §112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

This approach, however, would make the 'law of nature' exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. [citing *Bilski*; *Diehr; Flook; Benson*] See also H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) ('A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled' (emphasis added)).

We recognize that, in evaluating the significance of additional steps, the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

Mayo v. Prometheus, 132 S.Ct. at ____.

There is nothing inconsistent with the proposal, here, and the statement quoted from *Mayo v. Prometheus.* In the first instance, the guidance in *Mayo* speaks in the context of validity determinations in the courts and not about examination. Secondly, the proposal, here, does not preclude an examination under Section 101: Only the *order* of examination follows the classic patentability determination that has been the hallmark of the Patent Office since it opened its doors nearly 180 years ago in 1836.

(No hint or suggestion should be even remotely implied as to the incumbent leadership of any influence from Google. Years from now, the legacy of the incumbent leader of the Office will be viewed in the context of history as perhaps the most anti-patentee leader of in its entire history. The fact that the incumbent Under Secretary spent much of her career in a leadership position at Google is important only from the standpoint that Google during her tenure was constantly in a position of defending patent infringement charges so that her anecdotal, actual patent experience has been focused on this point of view. In terms of whether Google has any political influence over the Under Secretary, there is no evidence of any kind that this has occurred: To the contrary, her departure from Google was under circumstances that, if anything, would suggest a hostility toward Google.)

§ 1[c] Manufacturing and Electronics Industries

Top Ten Domestic Patentees (2013)*

Rank (U.S.)	Rank (All)	Company	Total Patents
1	1	IBM	6788
2	6	Microsoft	2814
3	10	Google	2190
4	11	Qualcomm	2182
5	12	General Electric	2086
6	15	Apple	1775
7	17	AT&T	1658
8	18	General Motors	1621
9	21	Hewlett-Packard	1459
10	23	Micron Technology	1280

* Source: IPO "Top 300" Listings for 2013. Unranked companies had less than 95 patents granted.

The largest users of the patent system, all from *outside* the pharmaceutical and chemical industries, are the big winners of the Leahy Smith America Invents Act. Such applicants now obtain an iron clad patent-defeating date against junior applicants without the possibility of a costly patent interference. As shown in the chart above, the Top Ten domestic patentees on average had 2385 patents granted in 2013.

Much of the worth of the patent portfolio for the largest filers is defensive in nature. To the extent that a defensive patent right is the goal for a particular application, this can now be safely obtained merely by filing a patent application that *discloses* the invention *without the need to prosecute the application:* The defensive right kicks in when the application is automatically published 18 months from the priority date, giving the published patent application a patent-defeating effect to deny novelty and nonobviousness retroactive to the priority date.

Previously, one had to obtain a patent to provide as basis for an interference because with a patent claiming the invention, the third party could not simply swear behind the applicant's filing date.

§ 1[d] Pharmaceutical Industry

The domestic pharmaceutical industry has long been operating on a *prospective* patent drafting basis as a first-to-file system so that there is virtually no adjustment that needs to be made for filing strategies for a domestic pharmaceutical company.

A new chemical entity proposed as a pharmaceutical requires expensive, extensive regulatory testing that can take many years and hundreds of millions of dollars before the first tablet can be put on the market. Here, the corporate research sponsor typically will develop *hundreds* if not *thousands* of promising new chemical entities where only a handful can be considered to be put through the regulatory testing gauntlet.

It is axiomatic that any drug candidate must pass *global* patentability muster, at least for the very top commercial countries for exploitation of pharmaceutical patents. This means as a minimum that there must be patent protection beyond the United States to include a European Patent and a Japanese patent – both under strict first-to-file regimes.

The patent focus of pharma has been on filing *few* applications but all of high quality, given the importance of a patent to the success of the product. The Top Ten filers – mainly European – obtained an average of less than 286 patents each in 2013:

Patenting by Top Ten Pharmaceutical Companies (by Revenue) (2013)[*]

Revenue Rank	Company	Country	Patent Rank (all)[**]	Pharma[**] Rank	Total[**] Patents
1	Johnson & Johnson	USA	29	1	1107
2	Novartis	European	119	3	287
3	Roche	European	82	2	458
4	Pfizer	USA	270	13	107
5	Sanofi	European	137	5	238
6	Glaxo SmithKline	European	224	10	129
7	Merck	USA	126	4	268
8	Bayer HealthCare	European	*Unranked*		<95[+]
9	AstraZeneca	European	*Unranked*		<95[+]
10	Eli Lilly	USA	*Unranked*		< 95[+]

* FiercePharma 2013, http://www.fiercepharma.com/special-reports/top-10-pharma-companies-2013-revenue

** Source: IPO "Top 300" Listings for 2013.

+ Lowest ranked "Top 300" organization had 95 patents granted.

§ 1[e] Academic Institution Patent Filing Regimes

The major academic research institutions of the United States symbolize the odd man out in the *Leahy Smith America Invents Act.* There is no other segment of the patent community that more stubbornly resisted the change to first to file. The academic research community topped matters off by gaining a grace period that was in reality anything but a success.

Only a thin fraction of the research work of a typical academic institution is suitable for patenting purposes. Since an academic institution needs either no or minimal defensive patent protection for its ongoing research work and since the academic institution does not itself manufacture products, its patent objectives should be focused upon *product* innovations that can be *exclusively licensed,* particularly new pharmaceutical products that are subject to regulatory review that make it difficult for competitors to design around a patented pharmaceutical product.

Yet, the patent filings by the leading academic institutions are *huge* particularly when contrasted with the low numbers of the leading pharmaceutical houses:

Top Ten Domestic Academic Institution Patentees (2013)*

Rank	Academic Institution	Total Patents
1	California (state system)	399
2	Massachusetts Institute of Technology	281
3	Stanford	170
4	Texas	169
5	Wisconsin (WARF)	160
6	California Institute of Technology	147
7	Columbia	104
8	Georgia Tech Research Corp.	98
9	Michigan	97
10	Illinois	97

*Source: Kevin E. Noonan, *IPO Names Top 100 Patenting Universities*, Patent Docs (July 24, 2014), http://www.patentdocs.org/2014/07/ipo-names-top-100-patenting-universities.html

§ 1[f] Impact of the New Patent Law

Until the *Leahy Smith America Invents Act*, domestic patent rights could often be saved by filing within one year of first public disclosure. Academic institutions created a unique triage model under the old law to first seek to sell or otherwise license an invention *before* a regular patent filing: Only if the invention could be sold *then* the patent process would commence. A generation ago, the system was modified to file what could be dubbed a "one hour" provisional application before the first public disclosure of the invention: The idea was that priority keyed to a provisional application is judged under a lower substantive standard than priority for a regular application. This misunderstanding was a creation of government and former government officials.

In essence, the task of winnowing out proposed patent applications was abdicated by a Technology Transfer Office (TTO) in favor of letting the marketplace decide by offering inventions to the marketplace within the one year grace period. (In contrast, the normal business decision in industry is made by a Patent Committee that performs the triage function *before* any first filing.)

The *Leahy Smith America Invents Act* has totally shattered the academic institution filing model because the "one hour" provisional application as basis for generic offensive claims is largely a myth; and, the grace period under the new law is sharply limited to the point where it cannot be relied upon as part of a routine, *prospective* strategy.

§ 1[g] Default Filing Decision *Before* any Prior Art Event

The decision whether to seek patent protection should *always* be made, whenever possible, *prior to* the public divulgation of an invention. Without a filing date, the disclosure of the invention in a "prior art" fashion *immediately* triggers an absolute bar to gaining a patent in most of the economically important overseas major countries of the world.

The United States under the *Leahy Smith America Invents Act* now operates under a true first-to-file system with a modified grace period. The label, "first-inventor-to-file" is just that, a label.

§ 1[h] The Big Picture: A Simple Presentation

A central feature of this writer's procurement practice is to provide a patent application for examination that is clean, simple and easy to examine. Given that an Examiner has only about one day for his first action search and examination, it is best to provide the examiner with, say, five claims and five prior art references with a clean presentation in the *Summary of the Invention* containing definitions of claim elements at the point of novelty. The one day for examination of this application will be more than sufficient for a *complete* examination that will air all apparent weaknesses and permit the examiner the feeling that he has indeed gotten all the issues needed on the table.

Contrast this simple presentation with a definitions-free presentation with fifty claims and fifty prior art references. There is little chance that the Examiner in his one day of search and preparation of a first action will provide a work product where the Examiner will be comfortable with the feeling that he has covered all bases. When an Examiner has this negative feeling toward an application, that the job is incomplete, this lessens the chance that the application will be allowed: The Examiner after all does not want to allow claims that do not pass patentability muster.

While special situations may require more complex drafting techniques, as a general rule the simple, easy to examine application will best suit the applicant's interests. It's not *how many* claims the applicant can gain but, rather, the *coverage* that can be obtained by the applicant that is key. This is the theme of the holistic approach set forth at § 11, *A Holistic, Claims-Focused Presentation,* and ensuing sections.

Above all, simple claims presented in a straight-forward manner permit the examiner the *time* to thoroughly examine the application and identify any real or apparent flaws in the claims. The real issues can be dealt with by amendment while the apparent flaws can be explained in Remarks that strengthen the prosecution history. *See* § 11[a][1], *Simple Claims and Straight-Forward Supporting Disclosure.*

The point has been raised that the applicant has a *right* to present as many claims as he or she chooses to present provided the necessary fees are paid. This is true. But, the examiner is under a strict system that requires a constant stream of disposals of applications which are never compensated by higher claiming fees. *See* § 11[a][5], *A Simple, Easy to Examine Patent Application.*

§ 2. First-to-File *sub nom* First-Inventor-to-File

§ 2[a] Cold Reality of First-to-File

During the lengthy six years gestation of the bills which ultimately ended up as the *Leahy Smith America Invents Act* there was much discussion of a "unique" American system of "first inventor to file".

The illusion was created that, somehow, the American system was unique, different from and better than a true first-to-file system. In fact, the American system *is* a first-to-file system whereby a senior inventor second-to-file who misses the race to the Patent Office by even one day has lost his patent rights against an independent inventor who has not derived the invention from the senior (but second-to-file) inventor. Or, the senior inventor loses his rights even if the junior inventor has not even entered the race to the Patent Office but simply *published* (or otherwise divulged) his invention in a manner to establish a prior art the day before the senior inventor files his patent application.

The *Leahy Smith America Invents Act* is indeed a major simplification and improvement over the prior law for many reasons, of which two complementary changes deserve special note.

First, winning the race to the Patent Office is now outcome determinative in the 99 % of cases that would have in any event been won in the "first inventor" system, simply because it was so difficult for a second inventor to establish priority under the old interference system. But, the new system is unlike the old system: Previously, a deep pockets second to file organization could wear down the first to file inventor and often gain a favorable settlement (or win); but now, the outcome

is determined early on because there is no possibility to prove an earlier date of invention.

Second, there are now powerful post grant trial proceedings available under Inter Partes Review (IPR) and Post Grant Review (PGR). Patents will continue to slip through the *ex parte* examination cracks in the system either through the absence of the best prior art being cited or glitches in the procurement proceedings; now, however, these patents can be promptly and successfully weeded out through the IPR and PGR proceedings.

Make no mistake about this: The system was designed for overall efficiency and those wishing to continue to take advantage of loopholes such as the grace period were not at the center of the legislative process. While everyone was able to testify, the remarks of the Senate leaders on the eve of enactment showed that they placed the greatest trust in the major mainstream players of the patent community. Thus, Senator Jon Kyl gave special cognition to Michael K. Kirk, Robert A. Armitage, Philip Johnson and Gary Griswold who collectively played a vital role in shaping the legislation as part of Senator Kyl's "kitchen cabinet."

As explained by Senator Kyl as the patent legislation was on the cusp of enactment: "[A]llow me to acknowledge the key members of the 21st Century Coalition for Patent Reform, who have devoted countless hours to this bill, and stuck with it through thick and thin. They have also formed an important 'kitchen cabinet' that has been indispensable to the committee's drafting of this bill and to the resolution of difficult technical questions. I thus acknowledge and thank Phil Johnson, Gary Griswold, Bob Armitage, and Mike Kirk for their key role in the creation of the America Invents Act." *Patent Reform Act of 2011*, 157 Congressional Record S1360, S1394 (March 8, 2011)(Remarks of Senator Kyl)

Senator Kyl singled out for recognition "Hayden Gregory of the American Bar Association, Laurie Self and Rod McKelvie of Covington & Burling, and Hans Sauer, Mike Schiffer, Bruce Burton, Matt Rainey, David Korn, Carl Horton, Steve Miller, Doug Norman, and Stan Fendley [and thanked] Todd Dickinson and Vince Garlock of AIPLA, and Jim Crowne, who was willing to come to the Senate to double check the draft enrolled bill." *Patent Reform Act of 2011*, 157 Congressional Record S1360, S1394 (March 8, 2011)(Remarks of Senator Kyl). He also noted for special recognition the leadership of the Intellectual Property Owners, specifically noting contributions of its Executive Director, Herbert C. Wamsley as well as Dana Colaruilli. *Id.* The current Director of the Detroit branch of the U.S. Patent and Trademark Office, Professor Christal Sheppard, played an important role within the House of Representatives as a top Congressional staff member. Her contributions were recognized by one of the principal Senate-side players, Senator Jon Kyl, who noted that "[i]n the House of Representatives, key staff include Christal Sheppard of Mr. Conyers's staff." *Patent Reform Act of 2011*, 157 Congressional Record S1360, S1393 (March 8, 2011)(Remarks of Senator Kyl).

To be sure, there were countless officials in the Executive Branch and staff members on the Hill who were instrumental in the passage of the legislation, none more important than Joe Matal from the standpoint of his intimate knowledge of the legislation at every step of the way. As the bill reached the stage of final enactment, the Chairman of the Senate Judiciary Committee recognized the work of Joe Matal: "I commend * * * Senator Kyl for helping get this [legislation] done. * * * I also commend the hardworking * * * staffs of other Senators,

including * * * Joe Matal * * * for their dedicated efforts." *Patent Reform Act of 2011*, 157 Congressional Record S1360, S1361 (March 8, 2011)(Remarks of Senator Leahy).

§ 2[a][1] Prospective Reliance on the Grace Period is Untenable

The "first inventor" system as a *prospective* tool for patent management is dead because of the limited value of the grace period under the new law. The academic community – particularly through the Wisconsin Alumni Research Foundation, the "WARF", put up a valiant fight to save the grace period as acknowledged by Senator Kyl: "The Wisconsin Alumni Research Foundation has played an important role [in the creation of the *Leahy Smith America Invents Act*], particularly with regard to the bill's enhanced grace period. I thank Carl Gulbrandsen, Howard Bremmer, Andy Cohn, and Mike Remington." *Patent Reform Act of 2011*, 157 Congressional Record S1360, S1394 (March 8, 2011)(Remarks of Senator Kyl).

Bluntly stated, however, popular blogster Gene Quinn is not incorrect when he says that "anyone who relies on the existence of a grace period really is foolish in the extreme." Eugene Quinn, *A Brave New Patent World – First to File Becomes Law*, IPWatchdog.com (March 16, 2013). (While the grace period *is* dead as a prospective filing strategy, the grace period *does* have limited but important advantages as explained in the following section.)

To be sure, there *is* a one year grace period that *does* provide certain safeguards for the inventor who has inadvertently (or otherwise) failed to file a patent application before divulging his invention in a manner to establish prior art.

But, the grace period should be relied upon only *retrospectively* where it is discovered that no patent application has been filed, and now an immediate filing is necessary with the *hope* that the grace period will save the applicant.

Among several scenarios that show the problematic nature of the grace period is the situation where the inventor explains his invention to an academic conference open to members skilled in the art. At the conference during the general open discussion, a close friend and colleague of the inventor proposes in a widely circulated email an *obvious variation* of the invention; the email publication is without secrecy to a large segment of those skilled in the art (and hence is prior art as a "printed publication"). Then, and only then, the inventor files a patent application on *his* invention: Under the literal wording of the statute, the friend's e-mail publication of the *obvious variation* is "prior art", and this prior art is *not* of the claimed invention, so that under the literal wording of the statute the grace period does not apply because the obvious variation is not "the claimed invention":

"A *disclosure* *** *of a claimed invention* shall not be prior art to the claimed invention [as having been patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention] if *** the *subject matter disclosed* had, before such disclosure, been publicly disclosed by *** another who obtained the subject matter disclosed *** from the inventor ***."

35 USC § 102(b)(1)(B)(integrating in brackets text from 35 USC § 102(a)(1)) (emphasis added).

To be sure, while the literal wording of the statute denies a grace period for the pre-filing disclosure by a third party of an obvious variant of the claimed invention, the matter is one of controversy where the opposing view is supported largely by "legislative history" arguments. Unless such opponents are successful in a test case yet to come, it is dangerous to *prospectively* rely upon the grace period.

§ 2[a][2] Academic Community Grace Period Support

The academic community has doggedly fought for a continuation of the grace period. The importance of the old grace period was perhaps best manifested by the extreme attempts several years ago to have the Patent Office make a *de facto* modification to extend the grace period to *two years.* The "two year provisional" was explained by the Director of the PTO. *See* David J. Kappos, Providing Inventors More Time and Options, U.S. Patent and Trademark Office publication "inventorseye" (November 2010), http://www.uspto.gov/inventors/independent/eye/201011/cover.jsp (herein: "inventorseye"). An excellent analysis of this proposal has been made by Courtenay Brinckerhoff, *USPTO Launches Extended Missing Parts Pilot Program,* PharmaPatents Blog (December 10, 2010), http://www.pharmapatentsblog.com/uspto-launches-extended-missing-parts-pilot-program/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+Pharmapatents+%28PharmaPatents%29. * * *

In the initial *Federal Register* publication of the two year provisional proposal, the Patent Office touts the advantages:

"A … benefit is added flexibility for applicants who may otherwise be forced to expend resources completing nonprovisional applications that may prove unnecessary given an additional year of commercialization efforts. Providing a longer time period … would give applicants more time to ascertain the value of their inventions, thereby helping applicants to decide whether to incur the additional costs associated with pursuing patent rights."
Request for Comments on Proposed Change To Missing Parts Practice, 75 Fed. Reg. 16750, 16751 (April 2, 2010), http://edocket.access.gpo.gov/2010/2010-7520.htm.

.

The PTO itself explains that applicants will be able to use the interval of pendency of the provisional up until the filing of the regular application for commercialization efforts:

[Another] benefit is better targeting of applicant resources to commercialization efforts at critical time periods, which efforts can ultimately result in creation of jobs as well as new products and services." *Id.*
* * *
[W]ith the 24 month "provisional", the applicant would simply file a provisional application with "at least one claim, and drawings, when necessary, to understand the invention", *then* commence commercialization efforts and *then* at 24 months from the priority date, bring in the services of a patent attorney to draft a set of claims to cover the invention.

The driving force behind the "two year provisional" was the powerful lobby of research universities which see the change in practice to be of importance to provide additional time to decide whether to invest in the expensive services of patent counsel to pursue patent protection for innovations developed within their university systems.

Perhaps the most outspoken support for the two year provisional came from the University of California:

"[The University of California] is comprised of ten research-intensive campuses, and is involved in the management of three national laboratories, each of which files patent applications on discoveries made in their laboratories. Strong and predictable patent protection can provide an incentive for industry partners to invest the effort and resources in developing a university invention into a useable product.

"Many university inventions, however, are very early stage, requiring additional research, time and resources before a company is interested in pursuing any of the myriad ways a technology can benefit the public. Until such time, the university must either tap into its limited resources to seek patent protection on promising, but early stage, inventions, or let the opportunity pass by. Any strategies that can help to limit or delay prosecution costs or provide greater flexibility in seeking patent protection for early stage, high-risk university inventions would be welcomed. Therefore, [the University of California] supports the proposed change to the missing parts practice. …"

Testimony of William T. Tucker, Executive Director Innovation Alliances and Services of the University of California, available at the PTO website, *Comments on Proposed Change to Missing Parts Practice*, supra.

The federal lobbying arm of 182 major research-intensive universities strongly underscores support for the proposal to give 24 months of commercialization activities *before* entering normal patent procurement:

"The Council on Governmental Relations (COGR) is an association of 182 U.S. research-intensive universities, affiliated hospitals and research institutes… We strongly support the effective 12 months extension of the existing 12-month provisional application period….. The ability to file provisional patent applications has been highly beneficial to the university community, particularly given the early stage nature of technologies typical of university inventions. The ability to have additional time to assess market viability and find commercial partners for further development would be of particular benefit to universities, and also consistent with the Administration's current emphasis on enhancing the commercialization of

university research.

The added flexibility provided by extending the response period for a missing parts notice would not only give university applicants more time to assess commercial value but also allow better targeting of resources for this purpose, as stated in the Notice. University patent budgets are under great strain, and we fully support measures such as proposed that may lead to greater efficiencies."
Testimony of Anthony DeCrappeo, Council on Governmental Relations (COGR) , available at the PTO website, *Comments on Proposed Change to Missing Parts Practice*, supra.

WARF went even further to propose what would require a statutory change:

"In fact, it would be better if the rule changes instituted a true 2-year provisional application process. While applicants would still need to act within 12 months for purposes of international filings, the opportunity to wait an additional year before filing a U.S. non-provisional application would be extremely valuable for applicants, as the additional time could advance the developmental stage of inventions appearing in the application (thereby advancing the value of the full disclosure and its public benefit), and ultimately improve the quality of both the applications and the resulting patents."

Testimony of Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation, available at the PTO website, *Comments on Proposed Change to Missing Parts Practice*, supra.

Texas A&M voiced strong support for the 24 month provisional:

"Given a relatively high cost to the [Texas A&M University System] for patent prosecution, decisions to pursue patent protection on a given technology are largely driven by the potential to secure a licensee. Any expansion of time available for determining the licensable potential of a given technology would be a benefit to university commercialization efforts and would be expected to reduce the numbers of applications that must be dropped for want of a licensee. …

"[T]he proposed rule would permit university applicants two years of commercialization efforts for a (current) total filing fee cost of $275 if the application is ultimately abandoned prior to the expiration of the two year term. Although filing fees are a relatively minor percentage of the total cost of preparing and filing a patent application, the deferral of fee payments during early commercialization efforts is certainly a benefit of the proposal.

"The [Texas A&M University System] is generally supportive of extended pendency periods for provisional applications. While believing that the proposed change could be accomplished in a more straightforward fashion by a change to the patent statute, the proposed rule change would be expected to confer a benefit to university commercialization efforts and is generally supported."

Testimony of Dr. Marilyn M Huston, Ph.D., J.D., Managing Counsel, Business Law and IP, Office of General Counsel, Texas A&M University System, available at the PTO website, *Comments on Proposed Change to Missing Parts Practice*, supra.

§ 2[a][3] Federal Circuit "Fudge Factor" Test Case

The cold reality of the narrow wording of the grace period has been a major blow to the academic patent community. While it is true that legislators have made comments seemingly supportive of a broader view of the grace period, the reality of the narrow scope of the grace period has been explained by Robert A. Armitage:

Armitage has dubbed the academics' proposed interpretation of the grace period as adding a "fudge factor" not part of the law.

Armitage, undoubtedly the single most important part of the patent reform process, particularly when measured over the past generation, has provided a detailed rebuttal to the academic community critics who are labeled "fudge factor" proponents. *Eli Lilly and Company [ ] Supplemental Comments to the United*

States Patent and Trademark Office [ ] Notice of Proposed Examination Guidelines Entitled: Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act, a supplemental submission to the *Request for Comments on the Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act*, 77 Fed. Reg. 43759-43773 (July 26, 2012), on behalf of Eli Lilly and Company by its Senior Vice President and General Counsel, Robert A. Armitage, to the Honorable David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, October 22, 2012.

For anyone thinking of reliance upon the hope of a test case to overthrow the Patent Office interpretation, the Armitage submission should be a "must read", a sobering reality check that a test case ruling against his position and that of the literal wording of the statute is far, far from a slam dunk proposition. *Id.*

§ 2[a][4] "Plan B" Post-Publication Grace Period Usage

While the grace period should never be *prospectively* relied upon sometimes things go wrong: Through inadvertence (or otherwise) there is an inventor's prior art disclosure of the invention before any patent application is filed. Here, as long as there is no third party disclosure of an obvious variant, the grace period remains effective. But, to minimize the chance that a third party will make a prior art disclosure of such a variant that would instantly kill the grace period, it is imperative that the applicant *immediately* file a patent application to minimize the chance that there will be such an intervening third party publication.

Another problem arises where the first priority application *does* precede publication but where a second priority application with new matter is filed after the publication. Here, the second application should be filed as soon as possible and in any event before a third party is able to publish on a variant not covered by the grace period:

Where claims are first fully supported only by a *second* sequential filing, it is imperative that secrecy be maintained for the invention until after the second filing, because otherwise a prior art disclosure before the second filing will be fatal to patentability unless the *first* filing fully supports the claims.

In the first instance, a provisional application is very easy to file, but *substantively* the right of priority based upon a provisional is judged under identical standards as in the case where the parent is a "regular" (non-provisional) application: "Claims enjoy the earlier filing date only if the provisional application provided adequate written description under 35 U.S.C. § 112, ¶ 1." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010)(Rader, J.)(quoting *New Railhead Mfg. v. Vermeer Mfg*., 298 F.3d 1290, 1294 (Fed. Cir. 2002)(Michel, J.)).

Where a claim is presented after the priority filing, the applicant must show "that he or she 'had invented each feature that is included as a claim *limitation*[.]'" *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1332 (Fed. Cir. 2009)(Dyk, J.)(quoting *New Railhead*, 298 F.3d at 1295)(emphasis added).

Finally, if the applicant needs to have generic coverage for his invention, it is important that the generic scope to be sought in a later application is fully supported in the first application: If a generic claim and corresponding generic disclosure are presented *after* the priority date – and where the priority application only discloses species – the generic claim is not entitled to priority based upon the species. *In re Ruscetta*, 255 F.2d 687 (CCPA 1958).

§ 2[a][5] Overseas Systems Operate without a Grace Period

The major patent systems of the world operate *without* a grace period to save the inventor who fails to file before there is a prior art, patent-defeating event. This means that if the United States first filing in the world is filed in a manner to rely upon the grace period, foreign patent rights are automatically forfeited because of the absence of an international grace period.

§ 2[b] An Evolving, More Difficult Body of Case Law

§ 2[b][1] Post-*Nautilus* Claiming Definiteness under 35 USC § 112(b)

For the first time in more than seventy years the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), reviewed the issue of claiming definiteness under what is now 35 USC § 112(b). Until the Federal Circuit creates a new, *Nautilus*-consistent test – either via an *en banc* decision or a set of consistent panel opinions over the coming years – the law in this area must be considered fluid.

There have now been several post-*Nautilus* opinions from the Federal Circuit, perhaps most importantly *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, __ F.3d __ (Fed. Cir. 2015)(Dyk, J.). Other cases include *Interval Licensing LLC v. AOL, Inc*., 766 F.3d 1364 (Fed. Cir. 2014)(Chen, J.); *DDR Holdings, LLC v. Hotels.Com, L.P*., __ F.3d __ (Fed. Cir., 2014)(Chen, J.); and *Biosig Instruments, Inc. v. Nautilus, Inc.*, __ F.3d __ (Fed. Cir. 2015)(Wallach, J.).

Dow Chemical takes a very strict viewpoint that claims should clearly define the boundaries of protection:

[T]here can be no serious question that *Nautilus*[, *Inc*. *v*. *Biosig Instruments*, *Inc*., 134 S. Ct. 2120 (2014),] changed the law of indefiniteness. This was indeed the very purpose of the *Nautilus* decision. * * *

*** The Court explained [that] "[i]t cannot be sufficient that a court can ascribe *some* meaning to a patent's claim; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters *post hoc*." *Id*. at 2130. * * *

[Where there are different ways to measure a parameter in the claim, t]he patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select. *See Teva* [*Pharm*. *USA*, *Inc*. *v*. *Sandoz*, *Inc*., 789 F.3d 1335, 1341, 1344-45 (Fed. Cir. 2015)] (holding claim indefinite where molecular weight could be measured three different ways and would yield different results and the patent and prosecution history did not provide guidance as to which measure to use). Particularly this is so where different approaches to measurement are involved. *See id*. at 1341, 1344-45. Thus, contrary to our earlier approach, under *Nautilus*, "[t]he claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *Interval Licensing LLC v*. *AOL*, *Inc*., 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citing *Nautilus*, 134 S. Ct. at 2130 & n.8).

* * *

[Where there are plural methods to determine a claim parameter, t]he question is whether the existence of multiple methods leading to different results without guidance in the patent or the prosecution history as to which method should be used renders the claims indefinite. Before *Nautilus*, a claim was not indefinite if someone skilled in the art could arrive at a method and practice that method. *Exxon* [*Research & Engineering Co*. *v*. *United States*, 265 F.3d 1371, 1379 (Fed. Cir. 2001)].

* * *

Under *Nautilus* … "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable *certainty*, those skilled in the art about the scope of the invention." 134 S. Ct. at 2124; *see also id*. at 2129 ("[W]e read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty."). Here the required guidance is not provided by the claims, specification, and prosecution history.

The *Biosig* case is excerpted below, and gives a seemingly brighter picture of *Nautilus.* When reading *Biosig*, however, one must bear in mind that the decision is sharply different from *Dow Chemical.* As explained in *Dow Chemical* at footnote 10:

"[*Dow Chemical*] is unlike *Biosig Instruments*, *Inc*. *v*. *Nautilus*, *Inc*., 783 F.3d 1374, 1377 (Fed. Cir. 2015). In *Biosig*, we held that the prosecution history, the language of the claims, and the knowledge of one skilled in the art demonstrated that 'a skilled artisan would understand the inherent parameters of the invention as provided in the intrinsic evidence' and that the claim term at issue 'informs a skilled artisan with reasonable certainty of the scope of the claim.' *Id*. at 1382-84."

As long as one understands that there is a conflict between *Biosig* and *Dow Chemical,* one may continue to observe the "reasonable certainty" test of *Biosig*:

On the one hand, the [Supreme] Court [in *Nautilus, Inc. v. Biosig Instruments, Inc.* [ ], 134 S. Ct. 2120 (2014),] noted, the definiteness requirement must take into account the inherent limitations of language. "Some modicum of uncertainty," the Court recognized, is the "'price of ensuring the appropriate

incentives for innovation.'" Id., 134 S. Ct at 2028 (quoting *Festo Corp*, 535 U.S. at 741). On the other hand, the Court explained, a patent must be precise enough to afford clear notice of what is claimed, thereby "appris[ing] the public of what is still open to them. Otherwise there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." Id. at 2129 [ ]. The Court further explained the policy rationale: "absent a meaningful definiteness check . . . patent applicants face powerful incentives to inject ambiguity into their claims." Id.

Balancing these competing interests, the Supreme Court held that "[t]o determine the proper office of the definiteness command, . . . we read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." Id. (emphasis added [by the Federal Circuit]). "The standard adopted" by the Supreme Court "mandates clarity, while recognizing that absolute precision is unattainable." Id. at 2129. It also accords with opinions of the Court stating that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter." Id. (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916) (emphasis added [by the Federal Circuit])).

§ 2[b][2] Ambiguity Keyed to Multiple Interpretation Possibilities

It is not uncommon for a particular claim element to be susceptible to both a broad and narrow interpretation. The Federal Circuit in earlier opinions had disposed of this issue by ruling that if a claim was open to both a broad and narrow interpretation, the narrower interpretation would govern.

The Patent Office has rejected this approach in the context of its own interpretation of patent claims under *Ex parte Miyazaki*, 89 USPQ2d 1207 (PTO Bd.App. & Int. 2008). Whether *Miyazaki* becomes established at the Federal Circuit or not will have to take into consideration the recent development of the case law from the Supreme Court in the *Nautilus* case. *See* § 2[b][1], *Post-Nautilus Claiming Definiteness under 35 USC § 112(b)* (discussing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), and its interpretation in *Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, __ F.3d __ (Fed. Cir. 2015)(Dyk, J.))

Circuit Judge Plager, in particular, sees a special problem in the area of precision claiming. *Enzo Biochem, Inc. v. Applera Corp.*, 605 F.3d 1347, 1348 n.2 (Fed. Cir., 2010)(Plager, J., dissenting from den. of panel rehearing)(quoting David J. Dykeman and Joanna T. Brougher, *File, Protect, Update, Defend*, Corporate Counsel, May 1, 2010, http:// www. law. com/ jsp/ cc/ Pub Article CC. jsp? id = 1202447671049); *In re Packard*, 751 F.3d 1307, 1316 (Fed. Cir., 2014)(Plager, J., concurring),quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

§ 2[c] Provisional Application Mythology Created by the Patent Office

It was the government itself that took the lead in directly or indirectly establishing the idea that there are lower disclosure requirements for patents claiming priority based upon a provisional application.

The "conventional wisdom" of the time was that "[t]he requirements for filing a provisional application are more relaxed than those for non-provisional applications. * * * [T]hese applications are not evaluated by a PTO examiner. * * * The lack of PTO analysis makes provisional applications relatively inexpensive to file, with fees currently set at $ 75 for small entities and $ 150 for others." James R. Barney, *An Overview of the Pros and Cons of Provisional Patent Applications*, 1 Yale Symp. L. & Tech. 2 (1999).

The U.S. Patent and Trademark Office (PTO) had taken the lead in announcing lower standards for priority based upon a provisional application. Even as of 2002, in its official website, the PTO reassured the public that a provisional application "provides simplified filing with a lower initial investment with one full year to assess the invention's commercial potential before committing to the higher cost of filing and prosecuting a non-provisional application for patent[.]" http://www.uspto.gov/web/offices/pac/provapp.htm [August 2, 2002].

The PTO lists twelve "cautions" to the use of a provisional but nowhere cautions users that a claim-like disclosure is necessary. The closest suggestion is that "the disclosure of the invention in the provisional application [should be] be as complete as possible. In order to obtain the benefit of the filing date of a provisional application the claimed subject matter in the later filed non-provisional application must have support in the provisional application." *Id.*

At the time the provisional system was created in 1994, a recently retired former PTO leader said that "[f]iling a provisional application provides a mechanism for protecting absolute novelty in Paris Convention countries worldwide. Consider, for example, the client who informs you on the day before he is to make a public presentation, complete with written handouts containing his name, about a new device that he would like to market." Charles E. Van Horn, *Practicalities and Potential Pitfalls When Using Provisional Patent Applications,* 22 AIPLA Q.J. 259, 301 (1994). The provisional is given as the answer: "[I]t would be possible to protect absolute novelty worldwide by filing a copy of the written materials with a cover sheet that reads 'Provisional Patent Application' on the day before the public presentation." *Id.* Provisional applications are described by a former Commissioner as being "low-cost and easily filed" that can be filed without professional representation. Gerald J. Mossinghoff, *The U.S. First-To-Invent System has Provided No Advantage to Small Entities*, 84 J. Pat. & Trademark Off. Soc'y 425, 426 (*2002)* . *See also* Gerald J. Mossinghoff & Vivian S. Kuo, *World Patent System Circa 20XX, A.D* . , 80 J. Pat. & Trademark Off. Soc'y 523, 543 (1998) ("[H]ere is where the United States provisional application comes into play.

By filing a complete technical disclosure of the invention, a small entity can readily secure priority rights in a first-to-file system without a major expenditure of resources. This then gives the small inventor a year in which to file a professionally prepared patent application.") The authors continue: "[A] n inventor can achieve a one-year period in which to evaluate the commercial value of the invention and the desirability of filing a professionally prepared regular patent application." *Id.* at 544.

Thus, the former leader of the Patent Office stated that:

"By filing a complete technical disclosure of the invention, a small entity can readily secure priority rights in a first-inventor-to-file system without a major expenditure of resources. *This then gives the small entity a year in which to file a professionally prepared patent application*." *Id.* at p. 428; emphasis added. Congress more recently invited a patent law expert to appear who said that "[s]ometimes the provisional patent filing is little more than a draft paper, a long-winded e-mail, or informal notes." *Id.* at p. 428; emphasis added.

This "long-winded E-mail" is stated to help the university community and provide a free year to create the patent application: "[E]ven universities with tiny budgets and without the availability of patent lawyers routinely protect their ideas well before they are communicated to outside collaborators. The filing of a provisional application allows the researcher up to a year to prepare and file a formal patent application, which will carry the filing date of the provisional application, as its effective date." *Id.*

The conventional wisdom of the day was that standards for a provisional application "are more relaxed" than for a regular application: "The requirements for filing a provisional application are more relaxed than those for non-provisional applications. * * * [T]hese applications are not evaluated by a PTO examiner. * * * The lack of PTO analysis makes provisional applications relatively inexpensive to file, with fees currently set at $ 75 for small entities and $ 150 for others." James R. Barney, *An Overview of the Pros and Cons of Provisional Patent Applications*, 1 Yale Symp. L. & Tech. 2 (1999).

In the context of biotechnology, the president of Celera told Congress that he had filed provisional applications on literally *thousands* of protein-encoding sequences. Testimony of J. Craig Venter, Ph.D. President and Chief Scientific Officer, Celera Genomics before the Joint Economic Committee, U.S. Congress,

June 7, 2000, 2000 Westlaw 19304599 ("Celera announced last fall that the company had filed provisional patent applications covering 6,500 identified protein-encoding sequences"). Dr. Venter explained that "[a] provisional application serves to notify the Patent Office that a discovery has been made in the event that there are other patent applications for the same discovery. * * * During th[e] twelve-month period [to file a regular application], Celera will decide with its pharmaceutical partners which genes are medically important enough to file patent applications." *Id.*

Typical advice which was given about last minute filings is explained in one publication:

"When patent rights can be lost if an application is not filed on time, it is better to file a hastily drafted application on time then a well prepared application after a critical bar date. In these circumstances, the initial draft should be filed as a provisional, since the fees are cheaper and the inventor does not want the patent office to examine this draft anyway. *The provisional application should then be replaced with a more carefully drafted regular application claiming benefit of the provisional application.*"
Bitlaw, http://www.bitlaw.com/patent/provisional.html [August 2, 2002](emphasis added).

Another writer states that the provisional "application can be assembled and filed quickly. Frequently, the attorney files it the same or next day that the client contacts the attorney about the technology. Consequently, it is easy to obtain a U.S. filing date prior to any proposed publication, sale or offer for sale of technology embodying the invention." D. Andrew Floam, *Provisional Patent Applications: Use Them Properly & You'll Get The Best Bangfor your Buck*, 6 NO. 9 Intell. Prop. Strategist 1 (2000).

Outside the mainstream of patent law, there has been a widespread mythology about the provisional as having a simpler standard that can be used in lieu of a regular application when time is tight. Certified public accountants are taught that "[t]he provisional application is especially beneficial in situations where the one-year grace period is almost expired and preparing and filing a formal application in time would be difficult." Barry A Cooper, *Intellectual property primer*, The CPA Journal, 1/02 CPA J. 4047, 2002 WL 14217291 (2002). In the insurance field for E-commerce, the sentiment is echoed:

"A provisional patent application does not require the formality of a non-provisional (regular) patent application and, especially when a business method patent is involved, can usually be filed in a much shorter period of time."

Tips for Protecting Business Method Patents in the United States, *E-Business Insurance Legal Report,* 1 No. 6 E-Bus. Ins. Legal Rep. 10 (2000).

In the context of internet technology, it is stated that "[m]any times, a provisional application is just a 'document dump', i.e., a shell or outline of a patentable idea, that can be filed inexpensively. However, a provisional application provides a 'priority date' for determining what is and is not 'prior art' for a later-filed utility application." George H. Gates & Jason S. Feldmar, *Internet Patents*, 610 PLI/Pat 403, 419 (2000) (citing 35 USC § 119(e)).

The authors continue: "Provisional filing practice is beneficial in various circumstances, especially where there is insufficient time to prepare a complete "utility" patent application, and substantial documentation describing the invention is available. For example, if a paper describing an invention is about to be published, presented publicly, or shown to some third party, the paper can be filed with little or no modification as a provisional patent application." See also Peter A. Jackman, *Adoption of a First-To-File Patent System: A Proposal*, 26 U. Balt. L. Rev. 67, 85-86 (1997) (footnotes omitted)("Provisional applications provide a simple and relatively inexpensive method of establishing an early priority date. Their minimum requirements allow most inventors to file the application themselves, or with minimal assistance, and thus make the PTO more accessible."

§ 2[c][1] Academic Community Reliance on the Provisional

For the past generation, provisional application mythology led to a system where many in the academic research community would file "one hour" provisional applications *before* making a decision whether to expend funds and energy on a "regular" application. See, e.g., Scott R. Carter, *Biotechnology Patents & Business Strategies in the New Millennium* in BIOTECHNOLOGY LAW, Carter 666 PLI/Pat 287 (2001)(explaining California Institute of Technology system of filing a "one hour" provisional application *before* deciding whether to file a regular application)("In most cases, provisional applications are filed by universities with no claims and with a limited amount of review by an outside counsel, and typically less than an hour of review. A member of the OTT staff, most are patent attorneys or agents, reviews each disclosure prior to filing a provisional.")

The premise to the "one hour" provisional usage is that a later, "regular" application would be entitled to priority based upon the provisional application because a lower *substantive* standard for priority exists for priority keyed to a provisional than if the first filing were a regular (non-provisional) application.

The idea is that after the "one hour" provisional is filed then the applicant would have one year for commercialization efforts that would involve explaining the invention and offering the invention for sale or license and then, *if successful* in finding a licensee, *then* a regular application would be filed dated back (under this theory) to the provisional application filing date.

§2[c][2] Former Grace Period Obviated "One Hour" Provisional Problems

Prior to the *Leahy Smith America Invents Act* the "one hour" provisional theory was not a major obstacle to obtaining *domestic* patent rights because even without priority to the provisional application, the one year grace period of the "first inventor" system often saved *domestic* patent rights.

§ 3 The Late Stage Continuing Application

Years after the first filing when an impasse has been reached with the Examiner, now is a time for out of the box, fresh thinking to create claims – either original or new – that will pass patentability muster.

There are no fixed rules for such a late stage filing, but there are several factors that should be taken into consideration.

§ 3[a] Earliest Refiling to Possibly Avoid a Statutory Bar

It is a myth that a continuing application with new matter can be filed at any time. The filing should ideally take place as soon as possible, prior to the creation of an intervening statutory bar. For example, if an application is refiled more than thirty months from the priority date, the automatic publication of the patent application 18 months from the priority date will automatically be prior art even prior to the *Leahy Smith America Invents Act* as a statutory bar publication under 35 USC § 102(b) against claims not entitled to priority to the earlier application.

Under the new law there are more situations of prior art such as an overseas public use that will be difficult to ascertain, but where caution must be exercised to avoid a statutory bar.

§ 3[b] Dealing with the Possibility of Intervening Prior Art

The first rule in filing a continuing application – whether labeled as a "continuation", "continuation-in-part" or "divisional" – is to deal with the very real prospect that there is some intervening publication or other prior art event that will defeat a new claim, unless that new claim is entitled to priority to the original application.

In some instances, it is manifestly obvious that there *is* an intervening prior art event which will defeat a claim that is not entitled to priority: In virtually every case that is refiled more than thirty months from the priority date there *will* be an intervening statutory bar publication to bar claims not entitled to priority.

§ 3[c] New *and* Old Claims in a Continuing Application

Consider the hypothetical situation where the applicant has discovered a new Framoyl alloy which contains from 0.2 to 0.8 percent ferric oxide, and the applicant now wishes to claim instead a range of from 0.2 to 0.9 percent ferric oxide.

The *correct* way to refile the application is to have claims and matching disclosure in the continuing application as follows:

1. A Framoyl alloy containing from 0.2 to 0.9 percent ferric oxide.
2. A Framoyl alloy of claim 1 having from 0.2 to 0.8 percent ferric oxide.

With the above couplet of claims, in a worst case scenario where it is discovered that there *is* an intervening publication that is prior art, this means that claim 1 is invalid – but claim 2, fully supported in the original application – survives.

If, instead, the applicant had changed the range in his refiling to only show the range of from 0.2 to 0.9 percent ferric oxide, then that claim would be invalid and there would be no written description basis for the defense line claim of 0.2 to 0.8 percent ferric oxide.

§ 3[d] A Few, Finely Focused Claims

The patent draftsman should present a continuing case in a manner which could ultimately be presented on appeal to the Patent Trial and Appeal Board or, if necessary, to the Federal Circuit.

Appellate presentation necessarily means a focused issue where *one* claim presents the entire story for the patent applicant. (If, say, five claims are presented on appeal the applicant can elect to argue only for claim, and let the remaining claims stand or fall keyed to claim 1.)

If a great deal of time has past since the original filing date, now the commercial focus of the invention can be more precisely pinpointed. A large generic scope of protection may no longer be needed. If there is a specific commercial product that is the center of attention, consideration may well be given to claiming *only* that product, if supported. (Or, if the specific product is not supported by naming or an example, the narrowest supported generic claim should be presented which embraces the product.)

§ 3[e] Identical Supporting Disclosure should be Maintained

To minimize the consequences of the possibility that an intervening prior art publication will be found, *all* supporting disclosure from the original filing should be carried forward *verbatim* into the continuing application – together with any added material. Thus, while new material may be added, nothing from the original specification should be deleted.

It should be recognized that *any change* in the scope of protection could be problematic, even if the disclosure is *narrowed*. *See* § 154, *Narrowed Range Barred by Intervening Disclosure* (discussing the application of *In re Ruscetta*, 255 F.2d 687 (CCPA 1958), to narrowing in *In re Lukach*, 442 F.2d 967, 968-70 (CCPA 1971)(Lane, J.)).

§ 3[f] Clear Demarcation of New vs. Old Text

Particularly where there *is* an intervening prior art publication, a preferred method of presentation that draws a sharp line of demarcation is to use headings such as:

Summary of the Invention

Detailed Description of the Invention

Where no new examples are added, all changed text should appear within the relatively short *Summary of the Invention* while the entire *Detailed Description of the Invention* should be a *verbatim* copy of the same text from the original application. The applicant can assure the Examiner in his Information Disclosure Statement that the only changed wording in the continuing application appears in the *Summary of the Invention* and the claims. This makes the task of examination much simpler than otherwise would be the case, so the examiner does not need to parse every word appearing in the *Detailed Description of the Invention.*

§ 3[g] A Tailored "Background of the Invention"

A *Background of the Invention* should rarely, if ever, be filed as part of an original application. This is in part due to the uncertainty as to the scope of coverage that ultimately will be needed and the uncertainty of the state of the art at this early date. Additionally, the *Background…* may be basis for a narrowed interpretation of patent claims or may even present an admission as to a "problem" that may be an admission of motivation to make the invention under *KSR International Co. v. Teleflex Inc*., 550 U.S. 398 (2007).

The situation is entirely changed where a continuing application is filed many years after the original filing. Here, a one or two paragraph *Background of the Invention* may very well provide the reader – the judge, for example – with a good introduction to the invention.

§ 3[h] Adding Disclosure to Support Nonobviousness

It is, of course, well settled that insufficient disclosure in a parent case in terms of 35 USC § 112(a) cannot be remedied by adding disclosure without loss of the parent filing date. It is yet another matter where the original disclosure *does* meet 35 USC § 112(a) requirements (and is maintained in the continuing application) but *additional* disclosure is added to support a showing of nonobviousness.

For example, if a claimed compound is distinguished over the prior art because it alone is an anti-cancer drug whereas the prior art does not have this utility, the anti-cancer utility can be included in the continuing application to show nonobviousness. (This assumes that the original disclosure, e.g., as an anti-fungal agent, is *maintained* as well. *See In re Kirchner*, 305 F.2d 897 (CCPA 1962)(Rich, J.); *In re Davies*, 475 F.2d 667, 672 (CCPA 1973).)

§ 4. Priority Keyed to a Parent Disclosure

The majority of all patents granted today are based upon one or more earlier priority applications which may be either a regular (non-provisional), provisional or foreign application. There is one common standard for priority based on all such applications.

One of the most difficult areas of patent law and practice involves new applications and crafting claims to benefit from the earlier disclosure of a parent case. In the first instance, this depends upon how the original, parent application is drafted. A skimpy provisional application often fails to provide basis for claims introduced for the first time in a later application. The *Steenbock* situation from the first half of the twentieth century remains a puzzle today: A parent application discloses a generic invention including species "A" and "B" but not "C"; a continuation-in-part application is filed claiming with a genus claiming the same species *also* reading on species "C": How is it that a foreign counterpart of the parent filed a year before the continuation-in-part but *identical* to the parent disclosure constitutes a statutory bar against the new generic claim when the prior art relied upon (species "A" or "B" in the intervening publication) is identical to the species in the priority application? . While this book focuses upon *first filings* without many of the frills normally found in a patent application, different ground rules apply for late stage continuing applications.

§ 4[a] Identical Substantive Standard for All Varieties of Parent Filings

The identical substantive standard is used to judge whether priority should be granted based upon any form of parent application, whether the parent is a regular (non-provisional) application; a Paris Convention priority application; or a provisional application. *See In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989)(Paris Convention priority); *In re Ziegler*, 992 F.2d 1197 (Fed. Cir. 1993)(*id.*); *Kawai v. Metlesics*, 480 F.2d 880, 885-89 (CCPA 1973)(*id.*); *Anderson v. Natta*, 480 F.2d 1392, 1399 (CCPA 1973)(*id.*); *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290 (Fed. Cir. 2002)(Michel, J.)(priority based on provisional application).

§ 4[b] Parent Disclosure Key to International Patent Regime Priority

In the international patent regime of the Paris Convention, there is no requirement for priority that the same invention claimed in the later application must also have been *claimed* in the earlier application. It is rather whether the same invention has been *disclosed* in the earlier application that is critical.

That claiming in the earlier application is not required is seen from the domestic statutory scheme that priority may be based on a provisional parent application while there is no requirement that the provisional application contain *any* claim. This is also consistent with the international patent regime where Paris Convention priority is based upon a common *disclosure* in the parent priority application: "Priority may not be refused on the ground that certain elements of the invention for which priority is claimed do not appear among the claims formulated in the [priority] application …, provided that the application documents as a whole specifically disclose such elements." Paris Convention Art. 4H (1967 Stockholm Revision, carrying forward provision first introduced in the 1934

London Revision). As explained in the authoritative treatise penned by the head of BIRPI (the predecessor to WIPO), "[i]t will suffice for the claiming of the right of priority in a subsequent patent application if the elements of the invention for which priority is claimed are specifically disclosed in the documents of the previous application *as a whole* (including the description of the invention, drawings (if any), charts, etc.)." G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967,* Art. 4H, note c (Geneva: BIRPI 1968).

§ 4[c] Literal "Word for Word" Support is *not* Required

It is axiomatic that while it is best to have literal support for a claim in the parent disclosure, priority may be based upon an earlier application without literal, word for word support in the parent for the claimed invention. "The invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112." *In re Lukach*, 442 F.2d 967, 969 (CCPA 1971)(citing *Henry J. Kaiser Co. v. McLouth Steel Corp.*, 257 F.Supp. 372, 429 (E.D. Mich.1966), *aff'd*, *Kaiser Industries Corp. v. McLouth Steel Corp.*, 400 F.2d 36 (6th Cir. 1968)); *see also Fields v. Conover*, 443 F.2d 1386, 1391 (CCPA 1971)(Rich, J.)(quoting *Lukach*, 442 F.2d at 969)("[T]he now-claimed subject matter 'does not have to be described in ipsis verbis [in the original application] in order to satisfy the description requirement of § 112[.]'").

That the patent challenger must go beyond showing a lack of literal support is explained in *In re Wertheim*, 541 F.2d 257 (CCPA 1976)(Rich, J.). In *Wertheim*, the court explained that "[t]he PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under § 112, then the statement of [*Lukach*, 442 F.2d at 969], that 'the invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage." *Wertheim*, 541 F.2d at 265.

§ 4[d] Claim by Claim Priority Determination

"To qualify for an earlier filing date, section 120 requires, inter alia, that the earlier-filed U.S. patent application contain a disclosure which complies with 35 U.S.C. § 112, p 1 (1994) for *each claim* in the newly filed application. Thus, this benefit only applies to claims that recite subject matter adequately described in an earlier application, and does not extend to claims with subject matter outside the description in the earlier application." *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1564 (Fed.Cir.1997)(emphasis added)(citing *Waldemar Link, GmbH & Co. v. Osteonics Corp*., 32 F.3d 556, 558-59 (Fed.Cir.1994)).

As explained in *Waldemar Link:* "[a daughter application under 35 USC § 120] can be entitled to different priority dates for different claims. Claims containing any matter introduced in the [daughter application] are accorded the filing date of the [daughter] application. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application." *Waldemar Link*, 32 F.3d at 558 (citation omitted)

§ 4[e] Priority is keyed to a Single Priority Document

As explained in *Studiengesellschaft Kohle v. Shell Oil*, "an applicant cannot combine multiple prior applications to obtain an earlier filing date for an individual claim[.]" *Studiengesellschaft Kohle m.b.H v. Shell Oil Co.*, 112 F.3d 1561, 1562 (Fed. Cir. 1997)(Rader, J.). *See also* MPEP § 706.02(k)(R-11 (2013)), *Provisional Rejection (Obviousness) Under 35 U.S.C. 103 Using Provisional Prior Art Under Pre-AIA 35 U.S.C. 102(e)*(citing *Studiengesellschaft Kohle v. Shell Oil*)("[A] claim in a subsequently filed application that relies on a combination of prior applications may not be entitled to the benefit of an earlier filing date under 35 U.S.C. 120 if the earlier filed application does not contain a disclosure which complies with 35 U.S.C. 112 for the claim in the subsequently filed application.")

Thus, as stated in *Studiengesellschaft Kohle v. Shell Oil*:

[The patentee says] that the district court erred in concluding that the disclosures of two earlier filed applications cannot be combined to acquire an earlier filing date under 35 U.S.C. § 120***.

***

Section 120 sets forth the requirements for a patent application to receive the benefit of the earlier filing date from a prior application:

"An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States ... which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application ... if it contains or is amended to contain a specific reference to the earlier filed application."

35 U.S.C. § 120. To qualify for an earlier filing date, section 120 requires, inter alia, that the earlier-filed U.S. patent application contain a disclosure which complies with 35 U.S.C. § 112, ¶ 1 (1994) for each claim in the newly filed application. Thus, this benefit only applies to claims that recite subject matter adequately described in an earlier application, and does not extend to claims with subject matter outside the description in the earlier application. See *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558-59 (Fed.Cir.1994). In other words, a claim complies with 35 U.S.C. § 120 and acquires an earlier filing date if, and only if, it could have been added to an earlier application without introducing new matter. See *Mendenhall v. Cedarapids, Inc*., 5 F.3d 1557 1566 (Fed.Cir.1993).

Under 35 U.S.C. § 112, ¶ 1, and consequently under 35 U.S.C. § 120 as well, an applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991). An applicant cannot show possession of an invention based upon a combination of several distinct previous applications unless he shows that one of the applications discloses the invention. See *In re Scheiber*, 587 F.2d 59 (CCPA 1978) (Baldwin, J., concurring). In other words, a claim that relies upon a combination of previously-filed applications is not to be entitled to an earlier filing date because the applicant has not demonstrated possession of the complete invention at the time of an earlier application. Id. 199 U.S.P.Q. at 785 ("[A]ppellant is asking [the court] to make the decision that various bits of his claimed invention are supported in the parent applications.... The majority opinion properly rejects this approach."). In sum, 35 U.S.C. § 120 requires an applicant to meet the disclosure requirement of § 112, ¶ 1 in a single parent application in order to obtain an earlier filing date for individual claims.

Studiengesellschaft Kohle v. Shell Oil, 112 F.3d at 1564.

To be sure, *Studiengesellschaft Kohle v. Shell Oil* was decided based upon *domestic* priority under 35 USC § 120 and not Paris Convention priority under 35 USC §119. However, under *Kawai v. Metlesics*, 480 F.2d 880 (CCPA 1973), the priority rules for Paris Convention priority under 35 USC § 119 generally follow the priority rules for domestic priority under 35 USC § 120. "Under [35 USC §] 119, the claims set forth in a United States application are entitled to

the benefit of a foreign priority date if the corresponding foreign application supports the claims in the manner required by section 112, ¶ 1." *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989)(citing *In re Wertheim*, 541 F.2d 257, 261-62 (CCPA 1976)]; *Kawai v. Metlesics*, 480 F.2d at 887-89).

The Court in *Gosteli* concluded "that claims [ ] are entitled to the benefit of their foreign priority date under section 119 only if the foreign priority application properly supports them as required by section 112, ¶ 1. An application relying on the benefit of an earlier filing date in the United States would receive the same treatment under 35 U.S.C. Sec. 120." *Gosteli*, 872 F.2d at 1011 (citing *Kawai*, 480 F.2d at 886).

§ 4[f] A Simple Test to Determine Priority Support

A simple test to determine whether a new claim in a daughter application is entitled to priority keyed to a parent disclosure under the "written description" requirement of 35 USC § 112(a) involves the following:

Consider the parent specification *as filed* and determine whether a presentation of the new claim of the daughter, if added to the parent case by amendment, would have been considered supported under 35 USC § 112(a) without addition of "new matter".

If the answer is "yes", then there *is* support for the priority claim.

If the answer is "no", then there *is not* support for the priority claim.

§ 4[g] "Possession" of the Invention as a Priority Requirement

An application may be denied priority to an earlier application even if the *identical* invention is disclosed in the priority application, but the priority application does not manifest "possession" of the invention under *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc) (Lourie, J.). . This is true both for a parent provisional application as well as a Paris Convention priority application. *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290 (Fed. Cir. 2002)(provisional parent application); *Kawai v. Metlesics*, 480 F.2d 880 (CCPA 1973)(Paris Convention priority application). *See* §7[g], *Parent Disclosure "Possession" is Required for Priority* (citing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed.Cir.1997); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997); *Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333 (Fed. Cir. 2010); *Goeddel v. Sugano*, 617 F.3d 1350 (Fed. Cir. 2010); *Bradford Co. v. Conteyor North Am., Inc.*, 603 F.3d 1262 (Fed.Cir.2010); *In re Gosteli*, 872 F.2d 1008 (Fed.Cir.1989); *Jepson v. Coleman*, 314 F.2d 533 (CCPA 1963); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991); *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.Cir.1995); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997))

§4[h] Patentability as a Condition for Patent-Defeating Effect

It is seemingly well settled that the patent-defeating date of a *published* patent application for common disclosure in parent and daughter applications is the filing date of the parent application. In a case involving the patent-defeating date of a *patent* (as opposed to published application) the case of In *Dynamic Drinkware, LLC v. National Graphics, Inc.*, __ F.3d __ (Fed. Cir. 2015)(Lourie,

J.), has denied the patent-defeating effect as of the parent filing date unless a *patentable invention* is disclosed in the parent and daughter applications. *Dynamic Drinkware* was decided under the pre-*Leahy Smith* provision of 35 USC § 102(e)(2) (relating to the patent-defeating date of a patent).

The holding was keyed to *In re Wertheim*, 646 F.2d 527, 537 (CCPA 1981), that it is a condition for reliance upon the parent date *of a patent* that the patent challenger establish that the *parent* have a disclosure supporting the *claimed* invention of the patent.

Would the same conclusion have been reached if the patent challenger had relied upon the effective date of the *published application* which falls under 35 USC § 102(e)(1)? It remains an open question whether *Wertheim* applies in the event a patent challenge was based on the *published application* as opposed to the patent.

More importantly, the new statutory wording of the *Leahy Smith America Invents Act* raises the fundamental question whether the *Wertheim* condition survives under the new patent law, as seen from the statute itself :

35 U.S.C. 102 Conditions for patentability; novelty.
(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

* * *

(2) the claimed invention was described in a patent issued under section 151 , or in an application for patent published or deemed published under section 122(b) , in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

* * *

(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application

shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

* * *

(2) if the patent or application for patent is entitled to claim a right of priority under section 119 , 365(a) , or 365(b) or to claim the benefit of an earlier filing date under section 120 , 121 , or 365(c) , based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

§ 5. Prophylactic Drafting to Mitigate Post Grant Challenges

§ 5[a] Creating an Environment for a Simple, Complete Prosecution

A "simple" best practices approach to patent drafting for a first application focuses upon *only* the matters *necessary* for the examination. This means presenting only claims *necessary* for protection (as opposed to filing twenty claims because there is no extra fee for that many claims). This also means citing the few – the three or four or so – most relevant prior art references (and not the eighty or ninety provided by the patent searcher). This also means the *absence* of nonstatutory features in the specification such as a *Background of the Invention*, "gist" of the invention and "problems" faced by the art.

With a "simple" presentation the Examiner will have *the time* to do a complete examination and expose any real or apparent weakness. The applicant can then amend to deal with real problems or beef up the prosecution history by explaining why a point is only an apparent weakness.

§5[b] Citation but not Characterization of the Prior Art

A patentee gets into trouble when he makes an incorrect characterization of the prior art during prosecution. At the stage of a voluntary citation of prior art there is *no* duty to *characterize* the prior art, but only a requirement to *cite* the most pertinent known prior art.

§ 5[c] "Claims First" Patent Draftsmanship

It is a simple axiom that every term used in the claims should find a *consistent* usage in the specification. The identical terms should be used in both the claims and the specification. The scope of the claims should be matched by a disclosure of corresponding scope.

While this axiomatic, fundamental principle is easy to understand, there are repeated cases where the specification has the appearance of having been drafted independently by a person other than the claim drafter. In reality, this is not likely the case. Rather, a considerable number of patent applications are drafted in a "convenient" manner by practitioners who want to keep their computers humming with the production of more words per hour. Thus, they may ignore the corollary that to provide consistent usage in the claims and the specification, *the claims must always be drafted first, always prior to picking up a figurative pen to draft the specification.* (Exceptionally, the specification may be drafted first where the *only* purpose of the filing is defensive and particularly where the *only* objective is narrowly framed to defensively protect a disclosed embodiment.)

It is quite natural, particularly for an "upstream" stage invention where the commercial species is yet to be developed, that there is an urge on the part of the practitioner to produce *some* work product throughout the drafting process: It is far easier to write up the specification than to make a prophecy as to the scope of protection needed by the claims.

That the "claims first" rule is not always followed is manifested by the numerous cases that come to the Federal Circuit where claims have been given a narrowed interpretation because the specification has a tangential focus not keyed to the claims.

§ 5[d] Avoiding Sideshows to the Main Event

A "simple" presentation also means avoiding extraneous features in the patent application. This means avoiding inclusion of a *Background of the Invention*, "gist", "problems" and other unnecessary and often argumentative features: The Examiner presented with an application containing such features will lead to a prosecution history that may focus on side issues, away from the essentials. The *Background of the Invention*, "gist", "problems" and other unnecessary features may trigger a debate on issues having nothing directly to do with the questions of novelty nonobviousness.

§ 5[e] Withholding a Showing of Nonobviousness for the PTAB Trial

It is not uncommon to find the situation where the main issue in *ex parte* prosecution is whether the Examiner has made out a *prima facie* case of obviousness. Here, it is advantageous to *refrain* from emphasizing unexpected results under *In re Papesch*, 315 F.2d 381 (CCPA 1963), or showings of objective indicia of nonobvious under *Graham v. John Deere & Co.*, 383 U.S. 1 (1966). (Of course, if the unexpected result is that a particular drug product has, say, an unexpectedly superior level of low toxicity, then the specification *should* recite that "the compound has low toxicity", as opposed to saying "the compound has remarkably better toxicity values than the prior art.")

If the ex parte prosecution becomes difficult at the stage of establishing an absence of prima facie obviousness, then, of course, a comparative showing can be submitted to gain allowance of the patent. But, it may be far better to simply focus the *ex parte* prosecution on the absence of a case of *prima facie* obviousness: In a worst case scenario, a continuing application can be filed to present such evidence even after a loss at the PTAB in ex parte proceedings.

But, consider the advantage of saving the showing of unexpected results for a PTAB post-grant trial:

If the evidence *was* presented to gain the patent, the patent challenger – particularly for an Inter Partes Review – has *unlimited time* to pick apart the evidence used to gain the grant of the patent. In some areas such as pharmaceuticals it may take *months* to conduct comparative testing. New tests may be devised that show the data in a different light. A top academic in the field may be retained to tinker with the experimental conditions and come up with a fact-based declaration to minimize the value of the original showing. Even the smallest mistake in the *ex parte* presentation of the evidence can be picked apart and amplified in testimony.

If the evidence *was not* presented to gain the patent, the patent challenger faces none of these problems.

§ 5[f] Cabining the "Broadest Reasonable Interpretation"

§ 5[f][1] Definitions to Cabin the "Broadest Reasonable Interpretation"

On the one hand, a "glossary" or "definition" of every term in a patent should *not* be a part of the drafting strategy. But, for an element of the claim at the point of novelty to distinguish over the prior art, here, the *Summary of the Invention* immediately after the first reference to the element should contain a *specific definition* of that element. For example:

"As the 'Framus' of the invention is meant…"

Without the specific definition, the patent challenger at the PTAB will attempt to show that the "Framus" has a broader meaning beyond what the applicant has intended and, if "reasonable", that definition should control in proceedings at the PTAB. If this broader definition moves the claim closer to the prior art, the equation is shifted in favor of the patent challenger.

While the PTAB operates under the "broadest reasonable interpretation" rule of claim construction, it is clear that a *specific definition* trumps this general rule of construction: "[P]atentees can act as their own lexicographers if they ''clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning.'" *Vasudevan Software, Inc. v. Microstrategy, Inc.*, __ F.3d __, ___ (Fed. Cir., 2015)(Linn, J.)(quoting *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012), quoting *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

Thus, where an element is given a *specific definition* in the *Summary of the Invention* this should bar a Patent Office interpretation of that element broader than this definition. As explained in *Microsoft v. Proxyconn:*

"In *Cuozzo*, this court held that the broadest reasonable interpretation standard in IPRs 'was properly adopted by PTO regulation.' [*In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1282 (Fed. Cir.2015), *pet. for reh'g en banc den,* __ F.3d __ (Fed. Cir. 2015).] * * *

"That is not to say, however, that the Board may construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles. *** Rather, '*claims should always be read in light of the specification* and teachings in the underlying patent.' [*In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010)]. * * * Even under the broadest reasonable interpretation, *the Board's construction 'cannot be divorced from the specification* and the record evidence,' *In re NTP, Inc*., 654 F.3d 1279, 1288 (Fed. Cir. 2011), and 'must be consistent with the one that those skilled in the art would reach,' *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999). A construction that is 'unreasonably broad' and which does not 'reasonably reflect the plain language and disclosure' will not pass muster. *Suitco*, 603 F.3d at 1260."

Microsoft Corp. v. Proxyconn, Inc., __ F.3d __ (Fed. Cir. 2015)(Prost, C.J.)

§ 5[f][2] Critical Limitations Should Appear in the Claim Elements

A limitation at the point of novelty should be included in an *element* of the claim and not in the *preamble* (unless that element is *also* recited as part of an *element*). Heretofore, the case law has provided for a fact-dependent analysis whether a feature in the preamble is merely a statement of intended use (and hence not a limitation) or is a limitation to the scope of the claim, which is always the case if the feature is expressed as an element.

The appellate case law has been a muddled mix of fact-dependent decisions as to whether a preamble should be a limiting feature ever since the *Corning Glass* opinion boldly announced that there is no legal "litmus test" to make the determination:

"No litmus test can be given with respect to when the introductory words of a claim, the preamble, constitute a statement of purpose for a device or are, in themselves, additional structural limitations of a claim. To say that a preamble is a limitation if it gives 'meaning to the claim' may merely state the problem rather than lead one to the answer. The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim."

Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989)(Nies, J.).

The *fact dependent* aspect represents a major reason why the Federal Circuit may be expected to give particular deference to Patent Office trial determinations that a preamble feature is *not* a limitation to the claims. *Novatek, Inc. v. Sollami Co.*, 559 Fed. Appx. 1011 (Fed. Cir. 2014)(Wallach, J.), is a typical example of the fact-dependent nature of the holdings in the *Corning Glass* line of case law:

"[A] preamble is generally construed to be limiting if it ''recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim.' *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1305 (Fed. Cir. 2005) (quoting *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002)). * * *

"Whether a preamble is treated as a limitation is determined by the facts of each case and upon an understanding of what the inventors actually invented and intended to encompass by the claims. *Catalina Mktg.*, 289 F.3d at 808."

Novatek v. Sollami, 559 Fed. Appx. at 1015. (The case is cited as merely exemplary of the line of recent case law and is NOT cited as precedent, as it, indeed, is *nonprecedential*.)

The case law at the District Court level involving infringement and validity determinations has provided mixed, fact-dependent answers to the question whether a particular feature in a preamble is or is not a limitation. In many cases, either interpretation would be considered "reasonable".

But, whereas a "reasonable" interpretation in a District Court may result in the choice of the feature in the preamble being a limitation, a *broader* reasonable interpretation would *not* include this feature as a limitation.

Accordingly, in a patent trial at the Patent Trial and Appeal Board where the "broadest reasonable interpretation" rule is applied in either an Inter Partes Review (IPR) or Post Grant Review (PGR), this could result in a feature in the preamble *not* being considered a limitation. *See Microsoft Corp. v. Proxyconn, Inc*., __ F.3d __ (Fed. Cir. 2015)(Prost, C.J.), citing *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1282 (Fed. Cir.2015)).

Under the "broadest reasonable interpretation" rule, the patent trial is more likely than not to come out with the Board choosing to treat the feature in the preamble as *not* being a limitation to the scope of the claim. In such a case, the claim will be closer to the prior art and, if the particular feature is necessary to establish patentability, the claim that would be sustained in the District Court would, here, be invalid under the "broadest reasonable interpretation" rule.

The case law on patent interpretation in the IPR and PGR proceedings follows the ground rules for patent interpretation that were set forth in the leading reexamination case law, including the *en banc* opinion in the context of reexamination by Chief Judge Markey thirty years ago in *In re Etter*, 756 F.2d 852 (Fed. Cir. 1985)(en banc)(Markey, C.J.). As he explained, "[i]n *In re Yamamoto*, 740 F.2d 1569 (Fed.Cir.1984), this court said that claims subject to reexamination will 'be given their broadest reasonable interpretation consistent with the specification, and limitations appearing in the specification are not to be read into the claims.' 740 F.2d at 1571. That standard is applied in considering rejections entered in the course of prosecution of original applications for patent. See *In re Prater*, 415 F.2d 1393, 1404-05 (CCPA 1969)." *Etter*, 756 F.2d at 858.

Etter as *en banc* precedent confirmed the *Yamamoto* claim interpretation principle keyed to the "broadest reasonable interpretation" standard for patent trials at the Patent Trial and Appeal Board in major part due to the at least theoretical right of the patentee to amend claims in post-grant proceedings:

"An applicant's ability to amend his claims to avoid cited prior art distinguishes proceedings before the PTO from proceedings in federal district courts on issued patents. When an application is pending in the PTO, the applicant has the ability to correct errors in claim language and adjust the scope of claim protection as needed. This opportunity is not available in an infringement action in district court...." *Etter*, 756 F.2d at 858 (quoting *Yamamoto*, 740 F.2d at 1572). *See also American Med. Sys. Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1363-64 (Fed. Cir., 2010)(Dyk, J., dissenting)("[W]e have not succeeded in articulating a clear and simple rule. Majority Op. at 1358; *see also* Patrick J. Flinn, *Claim Construction Trends in the Federal Circuit*, 572 PLI/PAT 317, 335-36 (1999) (characterizing the preamble limitations test as 'opaque' and without a set framework). As a result of the lack of clarity as to whether a preamble should be construed as limiting, our case law has become rife with inconsistency, both in result and in the articulation of the test. As the leading treatise on patent law observes, 'the decisions are difficult to reconcile.' 3 Donald S. Chisum, *Chisum on Patents* § 8.06[1][d] (2010)."(footnote omitted); *American Med. Sys. Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1363 n.2 (Fed. Cir., 2010)(Dyk, J., dissenting)("See *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed.Cir.2006) ('While it is true that preamble language is often treated as nonlimiting in nature, it is not unusual for this court to treat preamble language as limiting, as it is in this case.'); *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed.Cir.2003) ('Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.'); *Catalina Mktg*., 289 F.3d at 808 (Fed.Cir.2002) ('No litmus test defines when a preamble limits claim scope.'). Compare *DeGeorge v. Bernier*, 768 F.2d 1318, 1322 n. 3 (Fed.Cir.1985) (stating that '[g]enerally, and in this case, the preamble does not limit the claims'), with *Bell Commc'ns*, 55 F.3d at 621 (noting that the observation in DeGeorge that the preamble does not generally limit the claims 'can only have been descriptive, rather than prescriptive .... [O]ne cannot determine a preamble's effect except by reference to the specific claim of which it is a component')."

§ 5[g] Species Claim Focused on the Commercial Embodiment

To protect a commercially practiced embodiment a species claim should always be focused on that embodiment. If only the species has unexpected properties a showing of such unexpected results will be relevant to the species claim but not necessarily to a broader claim. *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011). A species claim to the commercial embodiment eliminates any problem of "nexus" as to objective indicia under *Graham v. John Deere & Co.*, 383 U.S. 1 (1966), being tied to the *claimed* invention. Cf. the "cup case", *In re Tiffin***,** 448 F.2d 791 (CCPA 1971)(per curiam)(on reh'g)).

With a species claim, the problems of "possession" or other support questions under Section 112(a) applicable to a generic claim are eliminated. Cf. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc)(Lourie, J.)).

A species claim drafted to clearly cover the commercial embodiment also minimizes issues of indefiniteness under Section 112(b).

§ 5[g][1] Early Stage Focus on the Species Claim

One strategic move open in a trial at the Patent Trial and Appeal Board where there is a species claim covering the commercial embodiment *along with* generic claims is to file a *disclaimer* of all claims other than the species claim, and to do so *early* in the trial, perhaps concurrently with the patentee's initial merits pleading.

§ 5[g][2] Late Appellate Stage Focus on the Species Claim

Even where the applicant expects to seek broad protection and to enforce the generic claims, the species claim leaves a fallback position. Even late in appellate proceedings at the PTAB the patentee can at any time file a disclaimer of the generic claims, leaving only the species claim in play on appeal. This can be accomplished either as appellant or appellee.

§ 5[h] Basis for a Second Application for Downstream Prosecution

At the end of prosecution for any important invention where a patent is about to be granted, it may be desirable to *also* file a *divisional* application to related subject matter that has been held patentably independent and distinct for restriction purposes under 35 USC § 121. This gives the applicant greater flexibility to make amendments or alter the course of prosecution to avoid a negative result at the Patent Trial and Appeal Board:

To keep the option open, in drafting the application one independent claim should be included in the original application to a second invention. For example, claims 1-7 may be directed to a product (which will be the elected invention) and claim 8 may an independent claim to the method of using the product of claim 1. At the time of the first action, a restriction requirement may be made, in which case "Group I" (claims 1-7) is elected without traverse, and the "Group II" (claim 8) invention remains pending until cancelled late in prosecution – and then concurrently made the subject of a divisional application.

Even without a restriction requirement, a second application may be filed to a "different" invention even with overlapping subject matter, *provided* a terminal disclaimer is filed. For example, a first patent to a method of treating "pork" is to a different invention than the identical method of treating "meat". *In re Vogel*, 422 F.2d 438 (CCPA 1970)).

§ 5[i] Consistent and Correct English Usage

The *Summary of the Invention* should, following the first recitation of a term – particularly for an element at the point of novelty – include a definition of a term that is open to multiple interpretations.

Consistent use of language is important: An element set forth in the claims should have the same meaning in both the claims and specification, including the *Summary of the Invention*, the *Detailed Description* and the *Abstract of the Disclosure*. Using the same language over and over again may be boring to the novelist but use of synonyms to make the language more interesting must be avoided. Great care should also be taken to make sure that the *correct* English is used. For example, if the invention is a flash baking process at near incineration temperatures the claim should recite heating dough "at" the very high temperature and not heating dough "to" that temperature. See *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004).

"It may seem merely a statement of the obvious to say that everything in the specification must be accurate and true, but it is an aspect of drafting that requires continual watchfulness." E.W.E. Micklethwait, *Brushing Up Our Drafting,* Trans. CIPA LXV p. 72 (1946-1947), *reproduced,* Cole, Paul, ed., FUNDAMENTALS OF PATENT DRAFTING, 155, 163 (CIPA 2006).

§ 5[j] Chart Showing Specification Support for Claim Elements

It is axiomatic that the patent drafter should leave notes in the applicant's file showing precisely where in the specification there is support for terms used in the claims which are *not* specifically defined in the *Summary of the Invention.* The chances are that by the time of the first action when an issue of claim support is raised in an Examiner's first action, a *different* practitioner will be handling the prosecution than one who drafted the application. Or, memories may fade after two or three years.

In any event, if there is sufficient ambiguity for the Examiner to reject a claim as lacking support, this means that *the Examiner* couldn't figure out the support: Will a fresh practitioner without prior participation in the drafting process have a better chance of doing so? (Or, even the same practitioner after several years since having drafted the application?)

Where the practitioner provides an answer to the Examiner that is in fact inconsistent with the drafter's intention and support, this may be a sufficient basis for the Examiner to withdraw the rejection. But, downstream, the careful opponent in a post grant proceeding challenging the patent at the Patent Trial and Appeal Board may be able to demonstrate that, in fact, there is now an inconsistency in the prosecution history. This may be a basis to challenge the claim under Section 112(b) as indefinite.

♦ ♦ ♦ ♦

§ 6 Role of the MPEP, the Manual of Patent Examining Procedure

This chapter is, if anything, a "how NOT to" chapter, instead of the general theme of this book which is "how to" draft a patent application.

Why, then, is this chapter a part of a "how to" book?

The reason for inclusion of this chapter is to demonstrate precisely *why* the *Manual of Patent Examining Procedure* should be studied strictly for precise procedural rules and for guidance in prosecution of an application, but *never* for guidance in how to draft a patent application.

§ 6[a] The *Manual* is the Examiner's Procedural "Bible"

In theory it is understood by practitioners that the patent law, regulations and case law are the authoritative sources for the interpretation of patent law and practice, and that the *Manual of Patent Examining Procedure* stands subservient to all three sources. Clearly, the *Manual* is a tertiary resource that has no value as an authoritative source to the extent that it is inconsistent with either the patent law or the *Rules of Practice in Patent Cases.*

But, in fact, many – if not the majority – of practitioners in their early years leading up to practice and the start of their patent careers have never made a comprehensive study of any of these higher sources of authority. They have instead comprehensively focused their study of patent law on the *Manual of Patent Examining Procedure.*

Why?

The reason is quite simple: The Patent Office in its materials explaining how to take the patent registration examination focuses upon the *Manual of Patent Examining Procedure* as the primary examination study guide. Examination questions are announced as coming from the *Manual*. Even at the registration examination itself, persons sitting for the examination are provided an electronic copy of the *Manual*. It is thus little wonder that the typical newly minted practitioner has a knowledge of patent law focused upon what is taught in the *Manual*.

The *Manual* historically has been the "bible" for training prospective patent practitioners: The *Manual* is the *primary source* for questions on the patent registration examination, so it is natural that the prospective patent practitioner – after all concerned about *passing the examination* – will focus his study on the *Manual*.

This section explores precisely what the *Manual* teaches in its MPEP § 608 that deals with disclosure requirements:

§ 6[b] *Summary of the Invention,* Prime Example of a Failed Teaching

MPEP § 608.01(d) Brief Summary of Invention

"37 C.F.R. 1.73 Summary of the invention. A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed."

Since the purpose of the brief summary of invention is to apprise the public *** of the nature of the invention, the summary should be directed to the specific invention being claimed, in contradistinction to mere generalities which would be equally applicable to numerous preceding patents. That is, the subject matter of the

invention should be described in one or more clear, concise sentences or paragraphs. Stereotyped general statements that would fit one application as well as another serve no useful purpose and may well be required to be canceled as surplusage, and, in the absence of any illuminating statement, replaced by statements that are directly on point as applicable exclusively to the case at hand.

The brief summary, if properly written to set out the exact nature, operation, and purpose of the invention, will be of material assistance in aiding ready understanding of the patent in future searches. The brief summary should be more than a mere statement of the objects of the invention, which statement is also permissible under 37 CFR 1.73.

The brief summary of invention should be consistent with the subject matter of the claims. ***

As one example of the shortcomings of the *Manual* as a teaching tool, consider the contents of what *should* be in a *Summary of the Invention* versus what the *Manual* says should be in the *Summary of the Invention*.

If properly drafted, the *Summary should* recite the elements of the claimed invention and include definitions of otherwise ambiguous terms particularly at the point of novelty. For generic coverage, the *Summary* should also name plural embodiments for an element of the claimed invention where only one is set forth in the *Detailed Description of the Invention*. In the case of novel chemical or biotechnology entities, a statement of specific usefulness should be provided.

Instead, the *Manual* cites to the relevant rule for the *Summary of the Invention* which says *nothing* about any of the above "best practices" features that *should* be included in the *Summary of the Invention*. Instead, the rule says that the

Summary of the Invention should recite the "nature" of the invention and recite "objects" of the invention.

Amazingly, the "nature" of the invention is required by the Rules of Practice: Nowhere is there any *definition* or even explanation in the *Manual* as to precisely what *is* the "nature" of an invention.

In fact, the "nature" of the invention disclosure requirement dates back all th way to the 1830's as a statutory requirement but has not been that has not been a part of the patent law since January 1, 1953, more than sixty (60) years ago.

Recitation of an "object" of the invention has no statutory basis and its usage has long been discredited in the case law. Recitation of an "object" is far from a harmless mistake: An "object" can be basis for a narrowed scope of protection.

§ 6[b][1] Tracing the Origins to the 1949 First Edition

Before considering what the *Manual* should *not* say, it is important to note what the *Manual* itself *does not* say about the content of a *Summary of the Invention.* Each of the following points *should be* in the *Manual* to reflect case law decisions over the past several decades. The absence of these features manifests a failure to update the *Manual:*

Thus, the Patent Office rule nowhere says that the *Summary of the Invention should contain* a verbatim recitation of claim language, *should contain* exemplification of alternate elements where an element in the claims has a limited disclosure, and *should contain* an express definition at the point of novelty,

particularly as a way to cabin the "broadest reasonable interpretation" of the claims.

To the contrary, in the original 1949 First Edition the *Manual* says that the invention should be broken down into sentences that "paraphrase" the claim language: "[T]he purpose of the general statement of invention is to apprise the public *** of the nature of the invention [so that] the statement should be directed to the specific invention claimed ***. That is, the subject matter of the claims taken as a unit should be *paraphrased* in a few clear, concise sentences or paragraphs, according to the extent and nature of the invention. ****" MANUAL OF PATENT EXAMINING PROCEDURE (1st ed. 1949), § 8-9-5, General Statement of Invention (quoting Rule 10.2, Summary of the Invention) (Dept. of Commerce 1st ed. 1949)(emphasis added).

Why paraphrase the claim language? What possible positive purpose is achieved by deviating from the claim wording? Many years ago a leading English patent expert explained:

"[M]ost people agree that in normal cases it is desirable to include in the early part of the specification some broad statement of the invention. Some suggest that the statement should not adhere to the words of the claim but I think any departure is liable to be dangerous. If one has spent time and thought bringing the claim to the best wording one can think of, it seems illogical to employ a second best for the statement of the invention."

E.W.E. Micklethwait, *Brushing Up Our Drafting*, Trans. CIPA LXV p. 72 (1946-1947), *reproduced*, Cole, Paul, ed., FUNDAMENTALS OF PATENT DRAFTING, 155, 162 (CIPA 2006).

None of these important elements for a *Summary of the Invention* is housed within Rule 73.

While the current, relevant *Manual* section is silent on confusing terminology the original 1949 First Edition included the mandate that "[a] term used in the claims may be given a special meaning in the description. No term may be given a meaning repugnant to the usual meaning of the term. *** *The use of a confusing variety of terms for the same thing should not be permitted*." MPEP § 608.01(o), *Basis for Claim, Terminology in Description* (1st ed. 1949)(emphasis added).

§ 6[b][2] What the Manual *Doesn't* but *Should* Require

§ 6[b][2][A] Verbatim Recitation of the Claim Language

As noted earlier, there are several key requirements for an optimum *Summary of the Invention,* including a verbatim restatement of the features of the *claimed* invention.

§ 6[b][2][B] Exemplification of Claim Elements

Where an element of a claim is performed with reference to only a single feature representing that element without setting forth plural features, case law has in some instances interpreted the element as limited to the single feature; here, the *Summary* should include *alternate* examples to ensure a broad scope of protection. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed.Cir.2005); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed.Cir.2001)).

§ 6[b][2][C] Definitions at the Point of Novelty

A term in the claim at the point of novelty may be expressly *defined* in the *Summary…*

§ 6[b][2][D] Cabining the "Broadest Reasonable Interpretation"

The Patent Office rule for claim construction at the Patent Trial and Appeal Board gives all terms their "broadest reasonable interpretation". This can be mitigated by an express definition of a term in the *Summary of the Invention.*

§ 6[b][3] "Nature of the Invention": No Current Statutory Basis

While there is no rule mandating a definitional section in the *Summary of the Invention*, there *is* a rule even today that mandates a disclosure of the "nature of the invention:

There is no better example of a provision in the first edition that was proper at the time that *remains* today – even in the Rules of Practice of Patent Cases – when long overruled either by statutory enactment or case law. The *Manual of Patent Examining Procedure* through its numerous revisions dating back to the original 1949 first edition provides a snapshot of the failure of the Office to update its guidance to keep in tune with statutory changes:

The original 1949 edition of the *Manual* includes a quotation from the Rules of Practice:

Summary of the Invention. A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed.

§ 608.01(d), *General Statement of Invention* (quoting Rule 73)(Original 1949 edition).

By 1961, the *same Rule 73* is recited in the same section of the *Manual* (since retitled as *Brief Summary of the Invention*). In addition, the following statement has been added to the *Manual:*

"[T]he purpose of the brief summary of invention is to apprise the public … of the nature of the invention[.] ***

The brief summary, if properly written to set out the exact nature, operation and purpose of the invention will be of material assistance in aiding ready understanding of the invention in future searches. See [§] 905.04. ***

The brief summary of invention should be consistent with the subject matter of the claims. ***

MPEP § 608.01(d), *Brief Summary of the Invention* (Third edition 1961).

§ 6[b][4] "Nature of the Invention": 1836 Statutory Basis

A "correct[ ]" indication of an invention's "nature" and "design" was introduced as a statutory requirement of the 1836 patent law as a codification of the case law interpretation of the 1793 Patent Act as explained in *Hogg v. Emerson*, 47 U.S. (6 How.) 437 (1848)(Woodbury, J.).

As explained in the Curtis treatise, the 1836 patent law made it a statutory requirement that a patent "shall contain a short description * * * of the invention

* * *, correctly indicating [the] nature and design [of the invention.]" George Ticknor Curtis, A Treatise on the Law of Patents for Useful Inventions, §221, p. 251 n.3 (Boston: Little, Brown, and Company 1873 (4th ed.))(citing *Hogg v. Emerson*, 47 U.S. (6 How.) at 482, and quoting from The act of Congress of July 4, 1836, c. 357, § 6: "[E]very patent shall contain a short description or title of the invention or discovery, correctly indicating its nature and design[.]").

The page cited by *Curtis* from *Hogg v. Emerson* puts the 1836 statutory origin of the requirement for a disclosure of the "nature and design" of the invention in perspective as part of the evolution of the requirements to define the invention:

"[T]he revising act as to patents, in July 4th, 1836, changed the phraseology of the law in this respect, in order to conform to this long usage and construction under the act of 1793, and required not in terms any abstract of the petition in the patent, but rather 'a short description' or title of the invention or discovery, 'correctly indicating its *nature and design*,' and 'referring to the specification for the particulars thereof, a copy of which shall be annexed to the patent.' And it is that—the specification or schedule—which is fully to specify 'what the patentee claims as his invention or discovery.' Sec. 5. (5 Statutes at Large, 119.)

It was, therefore, from this long construction, in such various ways established or ratified, that, in the present patent, the schedule, or, in other words, the specification, was incorporated expressly and at length into the letters themselves, not by merely annexing them with wafer or tape, as is argued, but describing the invention as an 'improvement, a description whereof is given in the words of the said John B. Emerson himself, in the schedule hereto annexed, and is made a part of these presents.' Hence, too, wherever this form has been adopted, either before or since the act of 1836, it is as much to be considered with the letters,— literae patentees, — in construing them, as any paper referred to in a deed or other contract.

Most descriptions of lands are to be ascertained only by the other deeds and records expressly specified or referred to for guides; and so of schedules of personal property, annexed to bills of sale. *Foxcroft v. Mallett*, 4 How. 378; 21 Maine, 69; 20 Pick. 122; Phil. on Pat. 228; *Earle v. Sawyer*, 4 Mason, C. C. 9; *Ex parte Fox*, 1 Ves. & Beames, 67. The schedule, therefore, is in such case to be regarded as a component part of the patent. Peters, C. C. 394, and Davis v. Palmer et al., 2 Brockenbrought, 301.

Hogg v. Emerson, 47 U.S. (6 How.) at 482 (emphasis added).

Prior to the reference in *Hogg v. Emerson* to the "nature of the invention" quoted above, the earlier history of the patent law and practice in both England and the United States is explained:

[T]he improvement referred to in the writ and in the letters-patent [in the current case], with the schedule or specification annexed, was in truth one and the same.

Coupling the two last together, they constitute the very thing described in the writ. But whether they can properly be so united here, and the effect of it to remove the difficulty, have been questioned, and must therefore be further examined. We are apt to be misled, in this country, by the laws and forms bearing on this point in England being so different in some respects from what exist here.

[T]he patent [as] first issued… contains no reference to the specification, except a stipulation that one shall, in the required time, be filed, giving a more minute description of the matter patented. (Webster on Pat. 5, 88; Godson on Pat. 6, App.) It need not be filed under two to four months, in the discretion of the proper officer. (Godson on Pat. 176.)

Under these circumstances, it will be seen that the patent, going out alone there, must in its title or heading be fuller than here, where it goes out with the minute specification. But even there it may afterwards be aided, and its matter be made more clear, by what the specification contains. They are, says Godson on Pat. 108, 'connected together,' and 'one may be looked at to understand the other.' See also 2 Hen. Bl. 478; 1 Webst. Pat. R. 117; 8 D. & E. 95.

There, however, it will not answer to allow the specification, filed separately and long after, to be resorted to for supplying any entire omission in the patent; else something may be thus inserted afterwards which had never been previously examined by the proper officers, and which, if it had been submitted to them in the patent and examined, might have prevented the allowance of it, and which the world is not aware of, seeing only the letters-patent without the specification, and without any reference whatever to its contents. 3 Brod. & Bingh. 5.

The whole facts and law, however, are different here. This patent issued March 8th, 1834, and is therefore to be tested by the act of Congress then in force, which passed February 21st, 1793. (1 Statutes at Large, 318.)

In the third section of that act it is expressly provided, 'that every inventor, before he can receive a patent,' 'shall deliver a written description of his invention,' &c.;—thus giving priority very properly to the specification rather than the patent.

This change from the English practice existed in the first patent law, passed April 10th, 1790 (1 Statutes at Large, 109), and is retained in the last act of Congress on this subject, passed July 4th, 1836 (5 Statutes at Large, 119).

It was wisely introduced, in order that the officers of the government might at the outset have before them full means to examine and understand the claim to an invention better, and decide more judiciously whether to grant a patent or not, and might be able to give to the world fuller, more accurate, and early descriptions of it than would be possible under the laws and practice in England.

In this country, then, the specification being required to be prepared and filed before the patent issues, it can well be referred to therein in extenso, as containing the whole subject-matter of the claim or petition for a patent, and then not only be recorded for information, as the laws both in England and here require, but beyond what is practicable there, be united and go out with the letters-patent themselves, so as to be sure that these last thus contain the substance of what is designed to be regarded as a portion of the petition, and thus exhibit with accuracy all the claim by the inventor.

But before inquiring more particularly into the effect of this change, it may be useful to see if it is a compliance with the laws in respect to a petition which existed when this patent issued, but were altered in terms shortly after.

A petition always was, and still is, required to be presented by an inventor when he asks for a patent, and one is recited in this patent to have been presented here. It was also highly important in England, that the contents of the petition as to

the description of the invention should be full, in order to include the material parts of them in the patent, no specification being so soon filed there, as here, to obtain such description from, or to be treated as a portion of the petition, and the whole of it sent out with the patent, and thus complying with the spirit of the law, and giving fuller and more accurate information as to the invention than any abstract of it could.

In this view, and under such laws and practice here, it will be seen that the contents of the petition, as well as the petition itself, became a very unimportant form, except as construed to adopt the specification, and the contents of the latter to be considered substantially as the contents of the former.

Accordingly, it is not a little curious, that, though the act of 1793, which is to govern this case, required, like that of 1790, a petition to be presented, and the patent when issued, as in the English form, to recite the 'allegations and suggestions of the petition,' (1 Statutes at Large, p. 321, sec. 1, and p. 110, sec. 3,) yet, on careful inquiry at the proper office, so far as its records are restored, it appears that, after the first act of 1790 passed, the petitions standing alone seldom contained anything as to the patent beyond a mere title; sometimes fuller, and again very imperfect and general, with no other allegations or suggestions, or descriptions whatever, except those in the schedule or specification. The only exception found is the case of Evans v. Chambers, 2 Wash. C. C. 125, in a petition filed December 18th, 1790.

Though the records of the patent-office before 1836 were consumed [by the fire in the Patent Office] in that year, many have been restored, and one as far back as August 10th, 1791, where the petition standing alone speaks of having invented only 'an easy method of propelling boats and other vessels through the water by the power of horses and cattle.' All the rest is left to the schedule. Other petitions, standing alone, are still more meagre; one, for instance, in 1804, asks a patent only of a 'new and useful improvement, being a composition or tablets to write or draw on'; another, only 'a new and useful improvement in the foot-stove'; and another, only 'a new and useful improvement for shoemaking'; and so through the great mass of them for nearly half a century. But the specification being filed at the same time, and often on the same paper, it seems to have been regarded, whether specially named in the petition or not, as a part of it, and as giving the particulars desired in it; and hence, to avoid mistakes as to the extent of the inventor's claim, and to comply with the law, by inserting in the patent at least the substance of the petition, the officers inserted, by express reference, the whole descriptive portion of it as contained in the schedule. This may have grown out of the decision of *Evans v. Chambers*, in order to remedy one difficulty there. Cases have been found

as early as 1804, and with great uniformity since, explicitly making the schedule annexed a part of the letters-patent. Proofs of this exist, also, in our reports, as early as 1821, in *Grant et al. v. Raymond*, 6 Peters, 222; and one, 1st Oct., 1825, in *Gray et al. v. James et al.*, Peters, C. C. 394; and 27 Dec. 1828, *Wilson v. Rousseau*, 4 How. 649.

Indeed, it is the only form of a patent here known at the patent-office, and the only one given in American treatises on patents. Phillips on Pat. 523. Doubtless this use of the schedule was adopted, because it contained, according to common understanding and practice, matter accompanying the petition as a part of its substance, and all the description of the invention ever desired either in England or here in the petition. Hence it is apparent, if the schedule itself was made a part of the patent, and sent out to the world with it, all, and even more, was contained in it than could be in any abstract or digest of a petition, as in the English form.

Hogg v. Emerson, 47 U.S. (6 How.) at 478-81.

The importance of the specification to interpret the scope of the patent right was emphasized by Justice Woodbury:

[W]hen we are called upon to decide the meaning of the patent included in these letters, it seems our duty not only to look for aid to the specification as a specification, which is customary, (1 Gall. 437; 2 Story, R. 621; 1 Mason, C. C. 477,) but as a schedule, made here an integral portion of the letters themselves, and going out with them to the world, at first, as a part and parcel of them, and for this purpose united together for ever as identical.

It will thus be seen, that the effect of these changes in our patent laws and the long usage and construction under them is entirely to remove the objection, that the patent in this case was not as broad as the claim in the writ, and did not comply substantially with the requirements connected with the petition.

From want of full attention to the differences between the English laws and ours, on patents, the views thrown out in some of the early cases in this country do not entirely accord with those now offered. Paine, C. C. 441; *Pennock et al. v. Dialogue*, 2 Pet. 1. Some other diversity exists at times, in consequence of the act of 1793, and the usages under it in the patent-office, not being in all respects as the act of 1836. But it is not important, in this case, to go farther into these considerations.

Hogg v. Emerson, 47 U.S. (6 How.) at 478-81.

§ 6[b][5] 1870 Law Mandating Claims to Define the Invention

Perhaps the "nature" of the invention disclosure requirement made sense in the early to mid-nineteenth century when claims were not mandatory as the definition of the invention. But, in the 1870 law that made the patent claim the mandatory feature to define the invention, the now-anachronistic "nature of the invention" requirement was maintained: "[E]very patent shall contain a short title or description of the invention or discovery, correctly indicating its *nature and design*…." *Long v. Rockwood*, 277 U.S. 142, 146 (1928)(McReynolds, J.)(quoting Chapter 230, Act July 8, 1870, 16 Stat. 201 (Rev. Stat. § 4884; section 40, Title 35, U. S. Code (35 USCA § 43; Comp. St. § 9428)).

§ 6[b][6] Definition of Infringement in the 1952 Patent Act

As explained in the *Aro* case, the 1952 Patent Act provided an express statutory definition of infringement as 35 USC § 271(a). *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 350 n.5 (1961). Regarding prior law, the Court in *Aro* explained that:

> Although there was no statutory provision defining infringement prior to [the 1952 Patent Act], the definition [of infringement] adopted is consonant with the long-standing statutory prescription of the terms of the patent grant, which was contained in § 4884 of the Revised Statutes as follows:
>
> "'Every patent shall contain a short title or description of the invention or discovery, *correctly indicating its nature and design*, and a grant to the patentee * * * of the exclusive right to make, use, and vend the invention or discovery throughout the United States * * *'" (Emphasis supplied [by the Court].)
>
> This provision is now contained without substantial change in 35 U.S.C. § 154, 35 U.S.C.A. § 154.

Aro, 365 U.S. at 350 n.5 (emphasis supplied in part by the Court and by this writer).

Quoting the words of the late Pasquale J. Federico, up through the eve of the effective date of the 1952 Patent Act, the statute required "a … description of the invention … correctly stating its nature and design." P. J. Federico, *Commentary on the New Patent Act* [1954], *reproduced at* 75 J. Pat. And Trademark Off. Soc'y 161, 201-02 (1993). But, the statutory basis for the "nature" and "design" disclosure requirement ceased with the effective date of the 1952 Patent Act: "The old statute [before the 1952 Patent Act] required 'a short title or description of the invention or discovery, correctly stating its nature and design'; this has been shortened to 'a short title of the invention' since the title is of no legal significance." *Id.*

§ 6[b][7] "Nature", a Term without Contemporary Meaning

The Federal Circuit has frequently spoken of the "nature of the invention" but has never defined what is meant by the terminology, even when this phase was used by the late Giles Sutherland Rich in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991)(Rich, J.), and *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1326 (Fed. Cir. 1991)(Rich, J.). In the former case he stated that "[t]he CCPA's 'written description' cases often stressed the fact-specificity of the issue. See, e.g., *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) ('The primary consideration is factual and depends on *the nature of the invention* and the amount of knowledge imparted to those skilled in the art by the disclosure')[ ]; …[*In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971)] ('What is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed').") *Vas-Cath,* 935 F.2d at 1562 (emphasis added).

In the latter case he said "[h]ow equivalency to a required limitation [to determine infringement] is met necessarily varies from case to case due to many variables such as … the *nature of the invention* ….") *Malta,* 952 F.2d at 1326 (emphasis added).

Other members of the Federal Circuit have cited the "nature of the invention" as significant but, again, without explaining what is meant by this terminology. *Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc*., 62 F.3d 1512, 1562 (Fed. Cir. 1995)(Nies, J., dissenting), *rev'd,* 520 U.S. 17 (1997)("The question of scope [of protection] is whether one of skill in the art would understand that a specific element of the claim is not the only means that may be used in the claimed invention. The answer depends on the *nature of the invention* [and other factors].")(emphasis added); *Pennwalt Corp. v. Durand-Wayland, Inc*., 833 F.2d 931, 962 (Fed. Cir. 1987)(en banc)(Newman, J., commentary)("[Under the doctrine of equivalents t]he range of equivalents depends upon the extent and nature of the invention.")(emphasis added); *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1322 (Fed. Cir. 2006); (Newman, J., dissenting)("It is not the law that process limitations are ignored in construing claims, whatever the nature of the invention.")(emphasis added); *Young Dental Mfg. Co., Inc. v. Q3 Special Products, Inc*., 112 F.3d 1137, 1144 (Fed. Cir. 1997)(Clevenger, J.)("The best mode requirement does not apply to 'production details.' … [U]nder the rubric of production details, we have referred to what more properly are considered routine details. Routine details are details that are apparent to one of ordinary skill in the art. See *Engel Indus., Inc. v. Lockformer Co*., 946 F.2d 1528 1532 (Fed.Cir.1991). They are appropriately discussed separately from production details because routine details do relate to the *quality or nature of the invention*.")(emphasis added); *EZ Dock Inc v. Schafer Systems Inc,* 276 F.3d 1347,

1351 (Fed. Cir. 2002)(Rader, J.)(quoting *Micro Chem., Inc. v. Great Plains Chem. Co*., 103 F.3d 1538, 1544 (Fed. Cir. 1997))("[A]ll of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the *nature of the invention*, must be considered and weighed against the policies underlying section 102(b)")(emphasis added); *Lough v. Brunswick Corp.*, 103 F.3d 1517, 1518 (Fed. Cir. 1997)(Lourie, J., concurring in den. suggestion for reh'g en banc)("[Section 102(b) public use] encompasses underlying facts such as … whether the nature of the invention was discernible by observation…")(emphasis added); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316 (Fed. Cir., 2005)(on reh'g)(Linn, J.)(quoting *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1378 (Fed.Cir.2003) ("It is not correct that nothing in § 102(b) compels different treatment between an invention that is a tangible item and an invention that describes a series of steps in a process. The very *nature of the invention* may compel a difference.")(emphasis added); *UMC Electronics Co. v. United States*, 816 F.2d 647, 656 (Fed. Cir. 1987)(Nies, J.)("All of the circumstances surrounding the sale or offer to sell, including …the *nature of the invention*, must be considered and weighed against the policies underlying section 102(b).")(emphasis added); *id.* 816 F.2d at 657 ("[W]e conclude from … the *nature of the inventor's contribution to the art*, that the claimed invention was on sale within the meaning of section 102(b).")(emphasis added); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)(Edward Smith, J.)(citing *Ansul Co. v. Uniroyal, Inc.*, 448 F.2d 872, 878-79 (2d Cir.1971))("The determination of what constitutes undue experimentation [in the context of enablement] in a given case requires the application of a standard of reasonableness, having due regard for the *nature of the invention* and the state of the art.")(emphasis added).

§ 6[c] Background of the Invention

MPEP § 608.01(c) Background of the Invention

The Background of the Invention may include the following parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions. The statement should be directed to the subject matter of the claimed invention.

(2) Description of the related art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A paragraph(s) describing to the extent practical the state of the prior art or other information disclosed known to the applicant, including references to specific prior art or other information where appropriate. Where applicable, the problems involved in the prior art or other information disclosed which are solved by the applicant's invention should be indicated. See also MPEP § 608.01(a), § 608.01(p) and § 707.05(b).

There is no statutory basis for this section, and some who *do* recommend such a section *do* say that one *should* provide a *Background of the Invention,* but then say that the *Background of the Invention* should be one "that says little or nothing substantive." Eugene Quinn, *Beware Background Pitfalls When Preparing a Patent Application,* IPWatchdog.com (October 23, 2011).

Under Rule 77(b)(5), it is suggested that a patent applicant "should" include in the patent specification a "[b]ackground of the invention". 37 CFR § 1.77(b)(5).

The Patent Office as part of Rule 77(b)(5), while saying there "should" be a *Background of the Invention* never says *what the content should be.*

Thus, there is nothing in the Rules that specify *what* must or should be included in the *Background.*

§ 6[c][1] "Field of the Invention"

The first part of the suggested *Background* ... is that there should be a "field of the invention". This is an anachronistic provision that is designed to help the *classification* clerk or examiner determine the proper *classification* of the application for assignment to the appropriate examining division or group. Thus, under the *Manual*, the "field" portion of the *Background* section is of "[a] statement of the field of art to which the invention pertains. This statement may include *a paraphrasing of the applicable U.S. patent classification definitions*." *Id.;* emphasis supplied.

§ 6[c][2] Prior Art "Information"

The *second* part of the *Background* is to provide a "[d]escription of the related art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98". This should comprise at least one paragraph "describing to the extent practical the state of the prior art or other information disclosed known to the applicant, including references to specific prior art or other information where appropriate.

§ 6[c][3] Discussion of "Problems" of the Invention

The *Background* provides that "[w]here applicable, the problems involved in the prior art or other information disclosed which are solved by the applicant's invention should be indicated."

§ 6[c][3][A] Problems with a "Background" Section

Provided the "information" important to an Examiner and required by Rule 56 is supplied in some form, it is completely unnecessary to supply a *Background* section in the patent application.

First of all, creating a *Background* section at the time of filing is very dangerous in the sense that there may be a false characterization of the true state of the art. At the time the application is filed, there remain some unpublished but prior filed patent applications that are thus completely unknown to the patent applicant; yet, *after* filing the application, when these applications are *published,* they retroactively become "prior art" under 35 USC § 102(e)(1). Then, the state of the prior art may be discovered to be different. Now, the original statement may be a misrepresentation of the true state of the art. Must there be an amendment?

Second, even if there is no mistake in the characterization of the invention, the characterization may create a narrowed interpretation for the scope of protection under the rules of claim construction.

In the *Reading & Bates* case, the patentee initially got in trouble by describing *his own work* as part of the "Summary of the Prior Art". *Riverwood Intern. Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1354-55 (Fed. Cir. 2003)(Linn, J.)(discussing *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645 (Fed.Cir.1984)). In the end, the patentee did win the case on the narrow basis that the work described was the patentee's own work. *Riverwood,* 324 F.3d 1346 at 1355 (The court "held that the patentee's discussion of his own patent in the specification section entitled 'Summary of the Prior Art' did not constitute an admission that the patent was prior art. In reaching its conclusion, the court reviewed our precedent and recognized the 'policy behind

requiring a statutory basis before one's own work may be considered as prior art.'")(citations omitted).

§ 6[c][3][B] *KSR*-Related Problems with "Problems"

The patent applicant who provides a "Background of the Invention" identifying a known problem in the art creates a problem under *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Admission that there is a known problem in the art invites the Examiner of the application or a court evaluating patent validity to conclude that the admission of the known problem creates a motivation to combine references, thereby rendering a possibly unobvious invention obvious.

"Evidence of a motivation to combine prior art references may flow from "'the nature of the problem to be solved.'" *Dome Patent L.P. v. Lee*, __ F.3d __ (Fed. Cir. 2015)(Hughes, J.)(quoting *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011), quoting *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004)).

As noted by the Chief Judge of the Federal Circuit, "[w]hen a claimed invention involves a combination of elements, however, any need or problem known in the relevant field of endeavor at the time of invention can provide a reason to combine. See *KSR* [550 U.S. at 420-21]. Moreover, the prior art need not address the exact problem that the patentee sought to resolve. Id." *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, __ F.3d __, ___ (Fed. Cir. 2014)(Prost, C.J.).

Institut Pasteur v. Focarino, 738 F.3d 1337 (Fed. Cir. 2013), points in the same direction:

"When there is a design need or market pressure to *solve a problem* and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Institut Pasteur*, 738 F.3d at 1344(quoting *KSR*, 550 U.S. at 421 (2007)(emphasis added).

In yet another case, the Federal Circuit explained that "our cases emphasize that 'where all of the limitations of the patent were present in the prior art references, and the invention was addressed to a 'known problem,' '*KSR* . . . compels [a determination of] obviousness.'" *Stone Strong, LLC v. Del Zotto Products of Florida.*, 455 Fed. Appx. 964, 969 (Fed. Cir. 2011)(quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1240 (Fed. Cir. 2010), citing *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 993 (Fed. Cir. 2009)).

In *Schwemberger* the admission in the specification of a known problem was a basis to reach a conclusion of unpatentability:

"The *specification … discloses a known problem* …. [M]odifying Pruitt's staple line configuration in accordance with the configuration disclosed by Schulze is no more than 'the combination of familiar elements according to known methods . . . [with] predictable results.' See *KSR* [*Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007)]; see also *id.* at 421 ('When there is *a design need or market pressure to solve a problem* and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.'). Therefore, the Board correctly determined that claim 9 is obvious over the combination of Pruitt and Schulze." *In re Schwemberger*, 410 Fed. Appx. 298, 304 (Fed. Cir. 2010)(emphasis added)

§ 6[c][3][C] PTAB Equates "Background" as "Admitted Prior Art"

In at least one case invalidity proceeding at the Patent Trial and Appeal Board, the Board has used the "background" section of a patent *and also the text of the provisional priority application* as critical "prior art" without statutory basis but rather as "admitted" prior art as seen from *Nichia Corp. v. Emcore Corp*., Case No. IPR2012-00005, paper no. 68 (PTAB 2014)(Chang, APJ).

In the *Nichia v. Emcore* case a critical basis for the combination of prior art references is the "glue" provided by the "background" section of both the patentee's granted patent *and also its provisional priority application;* this "glue" ties together the combination of references to establish unpatentability of the invention.

The holding in *Nichia v. Emcore* is stated at the conclusion of its opinion: "[The patent challenger] has met its burden of proof … in showing that claims 1-17 of the '215 patent are unpatentable under 35 U.S.C. § 103(a) over Kidoguchi, Nakamura, Fujimoto, Shibata, *and the Admitted Prior Art*." *Id.* at p. 64 (emphasis added)/

Earlier in a section Entitled "Admitted Prior Art" the Board explains:

The *Admitted Prior Art includes the background section* of the [ ] provisional application and the background section of the [ ] patent. In particular, the *background section* of the [ ] patent states that, in most semiconductor devices, the contacts **20** should exhibit low "ohmic" characteristics and low contact resistance. *** *According to the background section* of the [ ] patent, it was known at the time of the invention to form contacts for n-type GaN by annealing a Ti and Al structure. *The background section* of the [ ] provisional application states that "[t]ypical low work function metal/metal stack with yield low contact resistance to n-GaN on annealing is Al, Ti/Al."

Id., at 20-21, § II-B-2-e, *Admitted Prior Art* (emphasis added, citations deleted).

§ 6[c][4] Most Applicants Include a *Background*

There is no *statutory* basis to require a *Background of the Invention* and providing a *Background of the Invention* does not help the examiner with his examination of the application in a *Background of the Invention* that is *well drafted* to avoid admissions or any statement that would create a negative inference as to patentability. (This also assumes, of course, that the best prior art known to the applicant *is* cited in an Information Disclosure Statement).

Yet, the general view in the patent profession is that there *should* be a *Background of the Invention*, as seen from the advice given by the highly regarded patent expert, Jeffrey A. Lindeman, a top Silicon Valley patent firm and by Eugene Quinn, author of the most popular and widely read patent blog.

For example, Lindeman states that:

"Typically, the specification begins with a background section that provides the context for the invention. The background section can set out [the] problem the invention solves and discuss prior attempts to address the same problem. *** The background of the invention is a description to the extent practical of the state of the prior art or other information disclosed known to the applicant ***. Where applicable, the problems involved in the prior art or other information disclosed that are solved by the applicant's invention should be indicated [footnote omitted]."

Jeffrey A. Lindeman, *Patenting Amorphous Solid Dispersions of Pharmaceuticals*, § 13.4.1, *Describing Amorphous Solid Dispersions in a Patent*, in Ann Newman, ed., PHARMACEUTICAL AMORPHOUS SOLID DISPERSIONS, p. 422 (John Wiley & Sons, Inc. 2015).

The highly regarded Silicon Valley law firm referenced above explains that "[t]he *Background of the Invention* identifies and describes some of the problems solved by the invention. This section may also describe conventional solutions to the problems and the shortcomings of such solutions. It is not necessary for this section to provide an extensive overview and analysis of technical literature." Fenwick & West LLP, *Instructions for Reviewing Your Patent Applications, Background of the Invention* (2008), available at *https://otl.stanford.edu/documents/fw_patappreviewinstr.pdf* (last visited May 11, 2015).

Popular blogster Quinn elaborates on "some pitfalls to be on the lookout for when you are preparing the *Background of the Invention*." Eugene Quinn, *Beware Background Pitfalls When Preparing a Patent Application*, IPWatchdog.com (October 23, 2011). He counsels practitioners to "stay away from describing what the prior art is or does." *Id.* He warns that "[i]f you talk about what the prior art does *** you may find it exceptionally difficult to back away from positive, descriptive statements that have previously been made." *Id.* Even worse, "the more you explain about the prior art the more likely you will be making it easy for the patent examiner to issue an obviousness rejection. *** If you explain the prior art and the problems too well then your solution, and hence your invention, could seem obvious." *Id.*

Say nothing! Thus, Quinn says that "[t]he *Background* is supposed to be about the prior art *** but you won't [discuss the prior art] because of the pitfalls ***. You will only discuss in vague, cursory terms the prior art and only to the extent that it can be useful and NOT harmful. You must always remember the rampant problems inventors face when they lock themselves into a particular articulation of structural features and when they trivialize their own invention by making it seem obvious." *Id.*

§ 6[c][5] "Problems", "Objects" and "Advantages" for Japan Priority

In drafting a first United States application, it should be remembered that if the application is to serve as basis for a later Japanese convention application, it is helpful if the requirements of Japanese patent law are met as part of the United States priority application. Whether or not it is *necessary* that the Japanese substantive requirements are met as part of the priority filing, it is useful to include elements in the priority document that meet Japanese (and other overseas standards) because often the later Japanese or other overseas application are merely translated and neither revised nor tailored for Japanese or other differing standards.

Up until 1995 a point of great contention was the previous statutory requirement that the inventor must disclose in the specification an "object" of the invention, including a "problem that the invention is to solve". Until 1995, an applicant for patent in Japan under Art.36(iv) of the 1959 Patent Law *did*, as a matter of *statutory* law, have to state an "object" and "problem that the invention is to solve".

In 1995 Japan abolished its *statutory* requirement that the inventor must disclose in the specification an "object" of the invention, including a "problem that the invention is to solve". Before 1995, an applicant for patent in Japan under Art.36(iv) of the 1959 Patent Law *did* have to state an "object" and "problem that the invention is to solve":

"[Art.36(iv) of the 1959 Patent Law] stipulates that the detailed explanation of the invention shall state the 'objects'...of the invention in such a manner that it may easily be carried out by a person having ordinary skill in the art to which the invention pertains. Furthermore, under Examination Manual 25.01A, it is required that the 'objects' of the invention should be divided into three items proceeded by headings 'Industrial Field of Utilization', 'Prior Art', and 'Problem that the Invention is to Solve'.

"Consequently, the inclusion of 'objects' in a patent application is essential to the prosecution of the application or later interpretation of the granted patent."

Kenji Asai, Kanji Fujiyoshi, Fujihiro Kanda, Shuhei Katayama, Yoshihiko Kido, Shinichi Kimura, Hiroshi Kobayashi, Tomoya Kurokawa, Takao Matsui, Takanori Nakajima, Nobuyuki Nishikawa, Takeshi Nonaka, Toshiharu Ogawa, Makoto Onda, Yoko Sakuma, Takahisa Satoh, Yasumitsu Suzuki, Yukihisa Tamakushi, Yoshikazu Tani, Hitoshi Wada, Masashi Yanagida and Tamaki Yoshida, *Questions and Answers Regarding Japanese Patent Practic*e, Answer A7(1) to Question 7: "Missing 'Object': If you do not include 'objects' in a patent application, is such action detrimental to the prosecution of the application or later interpretation of the patent?", Japan Patent Attorneys Association**,** International Activities Committee (3rd ed. 2007)("Asai et al.")

Art. 36(iv) was amended in 1995 to abolish the requirement for an "object" and "problem that the invention is to solve":

"The revised [Art. 36(iv)] … stipulates that the detailed explanation of the invention shall state the invention, as provided for an ordinance of the Ministry of International Trade and Industry, in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains.

"Furthermore, Art.24-2 of Regulation [applicable since] July 1, 1995 stipulates that the description in accordance with the regulation as defined in the Patent Law Art.36(iv) shall be made by setting forth the features which are necessary for a person having ordinary skill in the art to recognize the technical significance of the invention, such as the problems to be solved by the invention and the solution therefore or the like.

Therefore, the statement of 'object', 'constitution and advantage' is not mandatory. The application is not rejected on the ground of mere 'omission of object'. In other words, the requirement for disclosure can be met, as far as a person having ordinary skill in the art upon filing can clearly recognize the technical significance of the invention from the description of 'The Detailed Explanation of the Invention', and can carry out the invention based on the description of 'The Detailed Explanation of the Invention'."

Id., Answer A7(2).

A statement of "advantages" of the invention was at one time important for a Japanese patent application, but this is no longer the situation. Priority should be granted in Japan whether or not the American priority document discloses "advantages" of the invention. As explained by the Japan Patent Attorneys Association:

The 1959 Patent Law in Art.36(iv) had a requirement that the specification state an "object" and "advantageous effect". Under the old 1959 law, it had been "recommended to state 'objects' of the invention as providing the alternative method in relation to the prior art. It [was] also advisable to state the 'advantageous effect' as being able to do something without using the conventional method."

Asai *et al.*, Answer A9(1) to Question 9: "**‘***Problems’ and ‘Advantageous Effects’, With respect to the specification, and the requirement to state ‘problems’ and ‘advantageous effects’, how should ‘problems’ and ‘advantageous effects’ be stated if the invention is simply another or alternative way of doing something, but there is no problem with prior art and the invention does not provide any significantly better efficiency, cost or results?***”,** Japan Patent Attorneys Association**,** International Activities Committee (3rd ed. 2007).

However, although the *statute* was changed, the practice was not updated to correspond to this statutory reform. An analysis of the Japanese practice in 1995 up to the present time is that although the statute which changed the official guidance from the Japan Patent Office makes it still advisable to include the features of the pre-1995 law as part of patent applications drafted today. (Unpublished study by Shozo Uemura and his group including Fumio Inai, Hironobu Kashihara, Shozo Yamashita & Tamaki Yoshida.) To be sure, at least some industry groups adhere to the idea that the statutory change was more significant than under the actual practice:

“Under the revised provision of Art.24-2 of Regulation which applies to patent applications filed on or after July 1, 1995, it is required to state either (i) the problems to be solved by the invention and technical means used for solving the problems, or (ii) the features which are necessary for a person having ordinary skill in the art to recognize the technical significance of the invention. Accordingly, if a so-called ‘problem-solution approach’ is not appropriate, it is not necessary to state [a] ‘problem.’ In summary, *it is sufficient that explanation is made in such a manner that a person having ordinary skill in the art can recognize the technical significance of the invention.*

“Under the revised provision of the Patent Law Art.36(iv) which applies to patent applications filed on or after July 1, 1995, statement of ‘advantageous effect’ is not required.”

Id. Answer A9(2); emphasis added.

The guidance from the Uemura group is consistent with the general rule today which, however, has significant loopholes, as discussed at §8[b][2], *Japanese Requirement to State "Problem" and "Solution"*.

§ 6[d] Abstract of the Disclosure

In most cases, the wording of the claims best describes the invention for anyone – whether the public or a patent practitioner. The *Manual* provides guidance that makes absolutely no sense. While the guidance is more fully quoted at the end of this section, several snippets are cited, here, that tell the whole story:

The public is told that that it should *not* focus on the wording of the claims but instead should explain "the nature and gist of the technical disclosure[.]" What, precisely is the "nature" or "gist" of the invention? Why, precisely should the *Abstract…* teach the "nature" or "gist" of the invention?

Furthermore, that the emphasis of the *Abstract…* is *not* on the invention but rather the "technical disclosure": Thus, the *Manual* states that "[a] patent abstract is a concise statement of the technical disclosure of the patent[.]"

The reader is told not to use "[t]he form and legal phraseology of ten used in patent claims" and, indeed, not to recite the claimed invention but, instead, "[t]he abstract should sufficiently describe the disclosure[.]"

The *Manual* thus provides the following guidance:

I. GUIDELINES FOR THE PREPARATION OF PATENT ABSTRACTS

A. Background

***

The content of a patent abstract should be such as to enable the reader thereof, regardless of his or her degree of familiarity with patent documents, to determine quickly from a cursory inspection of *the nature and gist of the technical disclosure* and should include that which is new in the art to which the invention pertains.

B. Content

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains.

If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure.

If the patent is in the nature of an improvement in old apparatus, process, product, or composition, *the abstract should include the technical disclosure of the improvement*.

***

If the new technical disclosure involves modifications or alternatives, *the abstract should mention by way of example the preferred modification or alternative*.

***

With regard particularly to chemical patents, for compounds or compositions, *the general nature of the compound or composition should be given* as well as the use thereof….

C. Language and Format

***

The abstract should be in *narrative form* and generally limited to a single paragraph within the range of 50 to 150 words. *** *The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.* The abstract should sufficiently *describe the disclosure* to assist readers in deciding whether there is a need for consulting the full patent text for details.

***

D. Responsibility

Preparation of the abstract is the responsibility of the applicant. Background knowledge of the art and an appreciation of the applicant's contribution to the art are most important in the preparation of the abstract. ***

MPEP § 608.01(b), *Abstract of the Disclosure* (emphasis added).

§ 6[d][1] No Penalty for an Abstract that Defines the Invention

There is no penalty against an applicant who files a proper statement of the *claimed invention* as the *Abstract of the Disclosure.* At worst, the Examiner may require a new *Abstract*….

§ 6[d][2] Abstract-Created Judicially Narrowed Claim Interpretation

Where the patent applicant drafts an *Abstract*… in accordance with the *Manual* different language will be used to describe the invention which can be used to *narrow* the effective scope of the claimed invention. *See Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000)(Bryson, J.); *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 965 n.2 (Fed. Cir. 2000).

§ 6[d][3] PCT Abstract Information

It is manifest that there is no close supervision of the *Manual* which in its nearly 3700 pages offers diametrically opposing viewpoints. This is no better illustrated than in the statements in one portion of the *Manual* that say that the "gist" of the invention must be disclosed, balanced by completely opposite statements elsewhere.

§ 6[d][3][A] "Pro-Gist" Requirements for PCT Applications

In the discussion of the Abstract for a PCT Application, MPEP § 1826, *The Abstract*, there is a section entitled *Summary of Abstract Requirements*, that states that the *Abstract.*

“Should contain:

(A) Indication of field of invention.

(B) Clear indication of the technical problem.

(C) Gist of invention's solution of the problem. …”

Thus the PCT requirement for an *Abstract* requires identification of a “gist of [a] solution,”, “the technical field” of the invention, a “technical problem” and “the gist of the solution of that problem.” *See* MPEP § 1826 (quoting PCT Rule 8.1(a)(i))(“The abstract shall [contain] a summary of the disclosure as contained in the description, the claims, and any drawings; the summary shall indicate the technical field to which the invention pertains and shall be drafted in a way which allows the clear understanding of the technical problem, the gist of the solution of that problem through the invention, and the principal use or uses of the invention[.]”).

§ 6[d][3][B] The “Anti-Gist” Reality Elsewhere in the *Manual*

Yet, in another portion of the *Manual* obviously written by a completely different team, inconsistent (but correct) advice is given in MPEP § 2141.02, *Differences Between Prior Art and Claimed Invention,* at § II, *Distilling the Invention down to a “Gist” or “Thrust” of an Invention Disregards “As a Whole” Requirement:* “Distilling an invention down to the ‘gist’ or ‘thrust’ of an invention disregards the requirement of analyzing the subject matter ‘as a whole.’ *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10 %

per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed)…."

§ 6[e] "Detailed Description of the Invention"

MPEP § 608.01(g) Detailed Description of Invention

A detailed description of the invention and drawings follows the general statement of invention and brief description of the drawings. This detailed description, required by 37 CFR 1.71, MPEP § 608.01, must be in such particularity as to enable any person skilled in the pertinent art or science to make and use the invention without involving extensive experimentation. An applicant is ordinarily permitted to use his or her own terminology, as long as it can be understood. Necessary grammatical corrections, however, should be required by the examiner, but it must be remembered that an examination is not made for the purpose of securing grammatical perfection.

* * *

The description is a dictionary for the claims and should provide clear support or antecedent basis for all terms used in the claims. See 37 CFR 1.75, MPEP § 608.01(i), § 608.01(o), and § 1302.01, and § 2111.01.

For completeness of the specification, see MPEP § 608.01(p).

§ 6[f] "[Best] Mode of Operation of Invention"

MPEP § 608.01(h) Mode of Operation of Invention

The best mode contemplated by the inventor of carrying out his or her invention must be set forth in the description. See 35 U.S.C. 112. There is no statutory requirement for the disclosure of a specific example. A patent specification is not intended nor required to be a production specification. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536 (Fed. Cir. 1987); *In re Gay*, 309 F.2d 769 (CCPA 1962). The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. *In re Honn*, 364 F.2d 454 (CCPA 1966). In determining the adequacy of a best mode disclosure, only evidence of concealment (accidental or

intentional) is to be considered. That evidence must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536 (Fed. Cir. 1987); *In re Sherwood*, 613 F.2d 809 (CCPA 1980).

The question of whether an inventor has or has not disclosed what he or she feels is his or her best mode is a question separate and distinct from the question of sufficiency of the disclosure. *Spectra-Physics, Inc. v. Coherent, Inc*., 827 F.2d 1524, 1532 (Fed. Cir. 1987); *In re Glass*, 492 F.2d 1228 (CCPA 1974); *In re Gay*, 309 F.2d 769 (CCPA 1962). See 35 U.S.C. 112 and 37 CFR 1.71(b).

If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the application was originally filed. *In re Hay*, 534 F.2d 917 (CCPA 1976). Any proposed amendment of this type should be treated as new matter.

Nowhere in this section is there any recognition of the *Leahy Smith America Invents Act* which provides that a violation of the "best mode" requirement is not basis for invalidation of a patent, nor that a defect in the "best mode" requirement may be overcome by filing a continuation-in-part that *adds* the best mode contemplated without loss of the right of priority.

♦ ♦ ♦ ♦

PART (II): DRAFTING THE APPLICATION

§ 7 First Application Elements in a First-to-File World

This discussion provides a guide for the prompt filing of a first application that will serve as the priority basis for what in most cases will be the application that will ultimately be granted as a patent: The majority of patents granted today claim priority to a first domestic or foreign filing – directly or through an intermediate parent. *See* § 7[a], *Unique Qualities of the First Priority Filing.* The first filing has unique qualities which must be taken into consideration in preparing the application. *Id.*

The state of the art is not fully known at the time of drafting the first application: The draftsman thus has a special challenge at the time of the first filing to determine the generic scope of protection. *See* § 7[b], *Scope of Disclosure for the First Priority Filing.*

There is little problem where the only objective is to protect an about to be disclosed embodiment and there is no interest in wider protection. *See* § 7[b][1], *Narrowly Defined Scope Known at the Filing Date.* The extreme other end of the spectrum occurs where only a prototype "upstream" product has been made, and the commercialized "downstream" embodiment is yet to have been made – or perhaps its structure has not even been identified. *See* § 7[b][2] *"Downstream" Protection at the "Upstream" Stage.* Where generic protection is to be sought defining the scope of protection may not be enough; there also may need to be a description of representative embodiments to establish "possession" of the genus. *See* § 7[b][3], *Establishing "Possession" in an Unpredictable Art.*

What greatly complicates the drafting process is first-to-file. Before the new law under the "first inventor" system if the applicant took, say, two months to prepare a patent application and in this interval a third party filed a patent application with interfering claims or disclosure, this was unfortunate but not necessarily fatal: The applicant could enter a patent interference and attempt to prove an earlier date of invention. Under first-to-file the delay may be fatal: Speed in filing the application is now a center stage criterion for drafting the first application. Such filing must focus on the *essential elements* necessary for priority of the specific embodiment. *See* § 7[c], *Earliest Possible Filing with Essential Elements.*

The basic "essential element" is a "cook book" example. This example provides a detailed explanation of an embodiment starting from the prior art all the way through to an end use. *See* § 7[c][1], *"Cook Book" Example of the Preferred Embodiment.*

Providing basis for a generic "claim 1" is only the tip of the iceberg. Beyond "claim 1", a narrowing, telescoping set of subgeneric fallback definitions should be provided to guard against the possibility that later encountered circumstances will mean that the broadest definition can no longer be sought. *See* § 7[c][2], *Best Possible Generic Disclosure.*

The importance of providing subgeneric definitions in the initial application is due to the fact that if one of the subgeneric definitions will ultimately be the broadest definition in the patent, that definition should find support in the original priority application. Failure to have such support could well leave the generic definition standing naked as of a later filing date because of lack of *Steenbock*

priority. *See* § 7[d][1], *Steenbock Requirement for Generic Support* (discussing *See In re Steenbock***,** 83 F.2d 912 (CCPA 1936)).

It is difficult to resolve the apparent conflict between the need for a *quality* first filing and a *fast* first filing. Reconciliation of these two opposing objectives is possible by a laser focus on the *essential* features of the patent application.

Another option is to file promptly with many but not all of the features ideally found in the specification. Here, the first filing should be a provisional while a *second* provisional is filed within, say, a few weeks with the remaining elements preferred for a first filing (while maintaining invention secrecy at least until such second provisional application is filed). *See* § 7[e], *Provisional Filing For Dual Priorities.*

Why are the filings made by following this book "better" than traditional filings? A lion's share of the answer is the narrow focus on *essential* features that are helpful to a valid and enforceable patent to the *exclusion* of a whole variety of elements some of which are even stated in the *Rules of Practice in Patent Cases,* but where such elements may, if anything, damage the scope of valid protection. *See* § 7[f], *Elements that Should NOT be in a First Filing***.**

Prior art information – whether in the application or a separate paper – should *not* be a part of any first filing. (Of course, if the application is a regular (non-provisional) application, an Information Disclosure Statement should be submitted within the three months from the filing date. *See* § 7[f][2], *Prior Art Information.*)

Simple words should be used when they correctly express the intended meaning of the author: "There are certain words I have never heard used in conversation or in a book, but somehow they are always cropping up in patent specifications. Words like "*thereto, therefrom, thereafter or thereup,"* sound more pompous than "*to it, from it, after it or up it*," but are they really any clearer? E.W.E. Micklethwait, *Brushing Up Our Drafting,* Trans. CIPA LXV p. 72 (1946-1947), *reproduced,* Cole, Paul, ed., FUNDAMENTALS OF PATENT DRAFTING, 155, 165 (CIPA 2006).

§ 7[a] Unique Qualities of the First Priority Filing

The typical patent today is *not* an original, first filing, but instead is a continuation, continuation-in-part or divisional of an earlier application or may claim priority to a provisional application or an overseas application under the Paris Convention. The original first filing has critical features that distinguish this filing from the later filing that ultimately results in the grant of a patent.

The original first filing should be *efficiently drafted*, containing a full disclosure of text *necessary* to establish priority for the ultimate application that will result in a granted patent. "Efficiency", here, translates into a better work product and the earliest possible filing date which is so important in a first-to-file world.

The original application should be drafted with the *presumption* that not all prior art information is known to the applicant at this time. Indeed, full knowledge of the state of the art is in part impossible – as in the case of still secret patent applications that will be published 18 months from filing, and then *retroactively* have a prior art date as of the filing date.

Full knowledge of the state of some prior art is in part *theoretical* as in the case of the *millions* of foreign language documents that have never been or have not yet been translated into English, particularly the hundreds of thousands of recent Chinese, Japanese and Korean published patent applications initially available as native language texts.

Given the fact that the complete state of the prior art is not known at the time of the first filing, it is impossible to state with precision the precise scope of generic protection that can be granted. Based upon the *assumption* that the best prior art is known, "claim 1" can be crafted to the limits of patentability *keyed to this assumption.* But, subgeneric defense lines to cover the important areas of protection should also be drafted to take into account the possibility that there may be prior art to knock out "claim 1". (If the first filing has *only* "claim 1" and species claims, if claim 1 is knocked out, there will be no priority basis for a new generic claim.)

§ 7[b] Scope of Disclosure for the First Priority Filing

Whether plural embodiments should be disclosed in support of a generic claim depends upon a variety of factors as discussed below:

§ 7[b][1] Narrowly Defined Scope Already Known as of the Filing Date

The scope of needed necessary protection may well be fully known at the time of first filing, as in the situation where the *only* objective is defensive to protect a *specific* about to be commercialized embodiment, without thought for exclusion of other embodiments. Obviously, *any* claim can be filed for such a first application, as the necessary prior art effect is created 18 months after filing through the automatic publication of the application, creating a novelty- and obviousness-defeating prior art effect as of the filing date.

§ 7[b][2] "Downstream" Protection at the "Upstream" Stage

At the other extreme is the situation of the about to be published "upstream" research results where an prototype product has been created but where more research is needed to establish a commercially viable "downstream" embodiment. Here, it is critical to have a generic *disclosure* sufficiently broad to capture "downstream" embodiments.

§ 7[b][3] Establishing "Possession" in an Unpredictable Art

Where the generic claim is broad it is useful to have representative examples supporting the full scope of the genus. *See* § 2[b], *Plural Examples for Generic "Upstream" Innovations.* In areas of highly unpredictable technology it is sometimes *necessary* to provide such representative examples. *See* § 2[b][1], *"Possession" as part of the "Written Description" Requirement* (discussing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc)(Lourie, J.)). *See also* §7[f], *Generic Support for an "Unpredictable" Ariad Invention* (discussing the sequential filing of a first provisional application with limited exemplary support complemented by a second provisional application containing representative exemplary support).

In an unpredictable technology such as biotechnology or pharmaceuticals, it may be necessary to craft prophetic disclosure of specific embodiments to establish "possession" of the generic invention. Failure to provide such "possession" disclosure may lead to invalidity of claims to a genus, even though the claim wording is taken *verbatim* from the priority application. It may not be enough in an *Ariad* situation that it may be obvious how to craft representative examples. *See* § 2[b][2], *"Possession" Obviousness not a Substitute for Original Disclosure.*

§ 7[c] Earliest Possible Filing with Essential Elements

It has always been important that the *first*, priority filing have the best possible disclosure of the invention: A failure to provide such disclosure may be fatal against claims which are not able to successfully claim priority to the first filing. But, this does not mean that the filing cannot be accomplished efficiently,

for at least most cases. (And, if an early filing is impossible for the full scope of disclosure needed, then an early provisional application should be filed, complemented shortly thereafter by a second application with all necessary features for full generic protection. Of course, secrecy must be maintained until the second application is filed.)

§ 7[d] Essential Elements for a First Filing

§ 7[d][1] "Cook Book" Example of the Preferred Embodiment

The first key features for a first filing is the "cook book" or "blue print" disclosure of the preferred embodiment. *See* § 9,*"Cook Book" Text of the Preferred Embodiment.*

§ 7[d][2] Best Possible Generic Disclosure

The first filing should contain at least one claim. This is because any application other than a provisional application must have at least one claim to gain filing date. (While a first case may be filed as a provisional without a claim, by doing so the risk is exposed that the case could be converted to a regular (nonprovisional) application and lose the filing date because of an absence of a claim.)

Most important is a *disclosure* that is the best approximation of the full scope of generic coverage needed, preferably with multiple, "layered" telescoping subgeneric scope disclosures (in the case of an offensive filing for broadest possible coverage).

§ 7[d][3] *Steenbock* Requirement for Generic Support

It is a serious mistake to file a first application with only a single, broad generic scope disclosure *and* species but *without* subgeneric layers of protection: If the generic scope falls by the wayside (such as through prior art that was not available at the time of the first filing), any subsequent application may not have *any* generic coverage. *See* § 4[b], *Steenbock Priority Keyed to the Same Invention* (discussing *See In re Steenbock***,** 83 F.2d 912 (CCPA 1936); *In re Ruscetta,* 255 F.2d 687 (CCPA 1958)(Rich, J.)).

The phenomenon where claims *beyond* claim 1 are neglected is not unique to American practitioners, as explained by the English expert Micklethwait:

"[W]e have arrived at our final wording for Claim 1. … It may be that we have decided to risk a claim broad to the borderline of vagueness, and possibly in somewhat functional form. … [O]f course, we cannot be certain that the claims initially filed will not be accepted as they stand.

"This leads on to the question of the second claim… which is often the weakest part of a shoddily-drafted specification. This is particularly apt to be the case where the first claim is a broad functional claim. It may be that the [applicant] has himself set out the purpose of the invention and the [practitioner] sees fit to claim in his first claim any structure achieving that purpose. Or it may be that the [practitioner] has himself dug out the matter for a broad first claim. Then he heaves a sigh of relief, like a man on the completion of an arduous and unpleasant task, and settles down lightheartedly to draft a series of constructional claims packed with arbitrary limitations and describing in more or less pictorial detail the specific constructions.

This is no good at all. If he sees fit to put in a broad functional first claim to anything fulfilling a given function, he must then analyse the specific constructions to see what in them represent the essential features for achieving that function."

E.W.E. Micklethwait, *Brushing Up Our Drafting,* Trans. CIPA LXV p. 72 (1946-1947), *reproduced,* Cole, Paul, ed., FUNDAMENTALS OF PATENT DRAFTING, 155, 161 (CIPA 2006).

§ 7[e] Provisional Filing For Dual Priorities

While it is optimum to file the first application with a generic disclosure exactly matching what should be the ultimate generic claim, it is often difficult (and sometimes impossible) to "guess" the scope of necessary generic coverage at the time of the first filing.

Here, it may be desirable to make the first filing a provisional application, followed by intensive study of what disclosure is needed (coupled with continued secrecy) and then providing the earliest possible *second* filing with the added disclosure.

Why not simply *wait* an added two months to file a single application as opposed to sequentially filing as opposed to filing twice? The answer is straight-forward: If one files an application disclosing even a single embodiment *before* a third party files to the same invention, then the filing with the single embodiment creates a statutory bar against the third party's claim reading on that species; on the other hand, if one waits two months to file a single application and that occurs *after* the third party application, then the entire generic invention is forfeited by the bar created by the third party's published application. The added cost of a second provisional is minimal with the usage of the provisional filing system: The second provisional application is a *verbatim* copy of the first application *plus* the new generic definition. In essence, the only added cost is the filing fee for the second provisional application.

§7[f] Generic Support for an "Unpredictable" *Ariad* Invention

Particularly in areas of an invention in the "upstream" phase where there have been few species reduced to practice, it is necessary to project the scope of the generic invention and – particularly where the technology is "unpredictable" – representative species should be disclosed to avoid denial of the generic claim for lack of "possession" of the genus. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). In theory, it would be advisable from the standpoint of support to take several weeks to craft representative examples, but this goes against the first-to-file need for an early filing date. The answer is to file a *first provisional* as soon as possible with perhaps only one example in hand, *maintain secrecy,* and then a few weeks later file a *second provisional* that has a disclosure of carefully crafted representative species that may well only be prophetic teachings.

Thus, where it is desirable to have plural, representative examples for a generic invention in an unpredictable art, one option is to file an application as a provisional as soon as possible with only the actual experimental work as supporting disclosure, but then to immediately have the inventor craft representative specific disclosures for species that will meet the disclosure standard of *Ariad*. Then, a *second* provisional should be filed as soon as possible with this additional prophetic disclosure.

Thus, a careful reading of *Ariad* shows that for an unpredictable area of technology it is important that a generic claim be supported by *disclosure* of representative embodiments, even if such representative embodiments, alone, are prophetic but which would be obvious to a worker skilled in the art. As explained by Circuit Judge Schall, "[t]o satisfy the written description requirement, 'the

applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that *by disclosure* in the specification of the patent.' *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541 F.3d 1115, 1122 (Fed.Cir.2008) (quoting *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed.Cir.1991))." *Novozymes v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013)(Schall, J.)(emphasis added).

The jurist who authored *Ariad* reiterated the same point in *Allergan, Inc. v. Sandoz Inc.*, __ F.3d __ (Fed. Cir. 2015)(Lourie, J.). Citing *Ariad* he stated that:

"The written description requirement is met when the disclosure 'allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.' *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). There is no rigid requirement that the disclosure contain 'either examples or an actual reduction to practice'; the proper inquiry is whether the patentee has provided an adequate description that 'in a definite way identifies the claimed invention' in sufficient detail such that a person of ordinary skill would understand that the inventor had made the invention at the time of filing (citing *Ariad* [*Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc)]. That assessment 'requires an objective inquiry into the four corners of the specification,' as 'the hallmark of written description is disclosure.' *Id.* at 1351." *Allergan. v. Sandoz*, , __ F.3d at __ .

Earlier, that same jurist had made the same point in *Abbvie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc*., 759 F.3d 1285 (Fed. Cir. 2014)(Lourie, J.). He emphasizes the importance of an original *disclosure* to support a genus in an unpredictable areas of technology:

"'[R]equiring a written description of the invention plays a vital role in curtailing claims ... that have not been invented, and thus cannot be described.' *Ariad*, 598 F.3d at 1352. '[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.' ' *Id.* at 1353–54 (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed.Cir.2004)). *** [T]he written description requirement with respect to particularly claimed subject matter is met if *the specification* shows that the stated inventor has in fact invented what is claimed, that he had possession of it. *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed.Cir.1991). We have stated that possession is shown by *disclosure in the patent*. *Ariad*, 598 F.3d at 1351 ('[T]he hallmark of written description is disclosure ... the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.')."

Abbvie Deutschland, 759 F.3d at1299 (emphasis added). This same jurist gives a further explanation in *Alcon Research Ltd. v. Barr Labs., Inc*., 745 F.3d 1180 (Fed. Cir., 2014)(Lourie, J.). He states:

We agree with [the patentee] that *the specifications* provide an adequate written description of the claimed invention. '[T]he hallmark of written description is *disclosure*. ' *Ariad*, 598 F.3d at 1351. The standard for satisfying the written description requirement is whether *the disclosure* 'allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.' *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed.Cir.2002). There is no requirement that *the disclosure* contain 'either examples or an actual reduction to practice'; rather, the critical inquiry is whether the patentee has provided a description that 'in a definite way identifies the claimed invention' in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing. *Ariad*, 598 F.3d at 1350, 1352;*Koito Mfg. Co. v. Turn–Key–Tech, LLC*, 381 F.3d 1142, 1154 (Fed.Cir.2004). That assessment 'requires an objective inquiry into the four corners of the specification.' *Ariad*, 598 F.3d at 1351.

Alcon Research, 745 F.3d at 1190-91 (emphasis added).

The point is not whether a representative example of the invention has actually been made in the laboratory but rather that the specification *discloses* that embodiment. As explained by Judge O'Malley in *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269 (Fed. Cir. 2012), where the patent challenger questioned the absence of an actual reduction to practice of the invention:

> [The patentee] is not required to prove an actual reduction to practice as to all disclosures. See *Ariad*, 598 F.3d at 1352. Instead, to satisfy written description, [the patentee] need only show that the specification itself demonstrates "a constructive reduction to practice that in a definite way identifies the claimed invention." See *id*. at 1352. The relevant inquiry, therefore, is whether a person of ordinary skill in the art would reasonably find that the patent sufficiently described the invention using [the disclosed features].

Streck, 665 F.3d at 1286.

Thus, it is *disclosure* of representative species – and not proof of their operability – that is key to providing a disclosure to meet the *Ariad* standard. This point is emphasized by Judge Prost in *Centocor Ortho Biotech Inc. v. Laboratories*, 636 F.3d 1341 (Fed. Cir. 2011)(Prost, J.). She notes that:

> [W]e have repeatedly indicated that the written description requirement does not demand either examples or an actual reduction to practice. *Ariad*, 598 F.3d at 1352. What it does demand is that one of skill in the art can "visualize or recognize" the claimed antibodies based on the specification's disclosure. [*Regents of the Univ. of Cal. v. Eli Lilly & Co*., 119 F.3d 1559, 1568 (Fed.Cir.1997)]. In other words, the specification must demonstrate constructive possession, and the [ ] patent's specification fails to do so. *Ariad*, 598 F.3d at 1352. [The patentee]'s asserted claims to fully-human antibodies "merely recite a description of the problem to be solved while claiming all solutions to it." *Ariad*, 598 F.3d at 1353. The actual inventive work of producing a human variable region was left for subsequent inventors to complete.

Centocor, 636 F.3d at 1353.

Since it is not necessary to prove an actual reduction to practice of the representative species, a constructive reduction to practice through a complete disclosure of such species should be sufficient. But, in view of case law it is important that prophetic experiments be recited in the present or future tense so there is no implicit representation that the experimentation has actually been carried out. This view of the law is exemplified in *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003)(Bryson, J.), where some of the experimental work in support of the claimed invention was blended together with actual laboratory work, yet the prophetic experimentation was stated in the past tense:

> Example VI [which involved prophetic disclosure] is written in the past tense. *** Each step of the example, over more than two columns of the patent, is described in the same fashion, using the past tense. ***
>
> * * *
>
> Misrepresentations by themselves are not enough to render a patent unenforceable; the misrepresentations must be intentional and they must be material to patentability. With regard to the element of intent, [the patentee] has not demonstrated clear error in the district court's finding [of misrepresentation through use of the past tense to describe prophetic examples]. The inventors attested that all statements made in the [ ] application were true. There was no suggestion by [the patentee] that the use of the past tense in Example VI was an oversight[.] ***
>
> [The patentee] attaches great significance to the fact that the district court found that the inventors had a good faith belief that they had discovered a different enzyme than that described in the prior art, arguing that "[b]ecause one cannot intentionally deceive by representing what one honestly believes, the district court's judgment cannot stand." [The patentee] misapprehends the import of that finding by the district court. The inventors may indeed have believed they had discovered a novel enzyme, but that belief does not permit them to make misrepresentations in seeking to persuade the examiner to issue a patent for that enzyme. Thus, the district court's finding that the inventors had a good faith belief in the novelty of their invention is not incompatible with a finding of deceptive intent.

Hoffmann-La Roche v. Promega, 323 F.3d at 1363-67. The case was followed three years later in *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc*., 438 F.3d 1123 (Fed. Cir. 2006)(Plager, J.):

[T]he case is similar to *Hoffmann-La Roche*. In that case, the patentees had erroneously stated in the written description that a procedure had been performed and presented "results" of that procedure. *Hoffmann-La Roche*, 323 F.3d at 1363. This court affirmed the trial court's finding of materiality, not on the ground that experimental results were required for patentability, but on the ground that the patentees misrepresented the results and made reference to them during prosecution in responding to a PTO office action. *Id*. at 1367-68. Similarly, the trial court's finding in this case was not based on Purdue's failure to provide scientific proof of its "surprising discovery," but on its failure to tell the PTO that the discovery was based only on the inventor's insight after suggesting during prosecution that the discovery was based on the results of clinical studies.

Purdue Pharma v. Endo Pharmaceuticals, 438 F.3d at 1133.

§7[g] Parent Disclosure "Possession" is Required for Priority

Should Paris Convention priority be granted where the invention in the United States application is *identical* to the invention disclosed in either an earlier provisional application or a Paris Convention priority document, where the *details* of the invention are not fully disclosed in the earlier application but which are *obvious* from the disclosure of the earlier application? The issue is yet one further example of a recurring theme set forth in *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.,* 298 F.3d 1290 (Fed. Cir. 2002)(denial of priority to a provisional application); and *Kawai v. Metlesics*, 480 F.2d 880 (CCPA 1973)(denial of priority to a Paris Convention parent application).

Here, because it was merely obvious how to make the invention that was not fully disclosed in the earlier application, priority is denied under *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc) (Lourie, J.), which represents a relatively new trend in the law in the United States. *Ariad* builds upon earlier precedent including *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed.Cir.1997), and the even earlier *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997). As explained in *Ariad*, "a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention." *Ariad*, 598 F. 3d at1356 (quoting *Regents of the University of California, v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed.Cir.1997)). As *Ariad* is an *en banc* precedent of the Federal Circuit, all panels of the Court are bound to follow this decision (unless and until overturned by the Supreme Court or by the Federal Circuit *en banc*).

For a regular (non-provisional) application to be entitled to priority based upon an earlier provisional or Paris Convention priority application, the priority application must *disclose* the invention. It is insufficient in the case of a generic invention that a specific embodiment *is* disclosed in the parent, and *other* embodiments are "obvious" in view of the specific embodiment. *See Anascape, Ltd. v. Nintendo of America, Inc.*, 601 F.3d 1333 (Fed. Cir. 2010); *Goeddel v. Sugano*, 617 F.3d 1350 (Fed. Cir. 2010), interpreting *Ariad*).

As explained in *Anascape:*

"To obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.'"
Anascape, 601 F.3d at1335 (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); and citing *Ariad*).

In *Goeddel v. Sugano* Sugano's Japan Paris Convention application was denied as basis for priority under the same rationale:

"Section 112 *** requires that the subject matter of [interference] counts be described sufficiently to show that the applicant was in possession of the invention. That a modified gene encoding the 166 amino acid protein could have been 'envisioned' does not establish constructive reduction to practice of the modified gene.

"The question is not whether one skilled in this field of science might have been able to produce mature [human fibroblast interferon] by building upon the teachings of the Japanese Application, but rather whether that application 'convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.' *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.Cir.2010) (en banc); *see also Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed.Cir.1997) (in claiming priority under § 120, '[a] description which renders obvious the invention for which an earlier filing date is sought is not sufficient'); *Bradford Co. v. Conteyor North Am., Inc.*, 603 F.3d 1262, 1269 (Fed.Cir.2010) (same)."

Goeddel v. Sugano, 617 F.3d at 1356.

California v. Eli Lilly case, *Regents of the University of California v. Eli Lilly* provides an explanation:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.' *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed.Cir.1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' *Lockwood*, 107 F.3d at 1572."

California v. Eli Lilly, 119 F.3d at 1566. In turn, the even earlier *Lockwood* case has a further explanation:

"Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See *Martin v. Mayer*, 823 F.2d 500, 504 (Fed.Cir.1987) (stating that it is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.') (quoting *Jepson v. Coleman*, 314 F.2d 533, 536 (CCPA 1963)). [The patentee] argues that all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention. [The patentee] accurately states the test, see *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991), but fails to state how it is satisfied. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. Id. ('[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or

she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.'). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used *in haec verba*, see *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.Cir.1995) ('[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims ....'), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient."

Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

§ 8 Elements that Should NOT be in a First Filing

A casual observer may think that the "safe" approach to filing a patent application is to make sure that every feature recommended or required by the *Manual of Patent Examining Procedure* is included in a best practices-drafted patent application.

Unfortunately, this is not true.

A variety of suggested or required features set forth in the *Manual of Patent Examining Procedure* do not have basis in the statute or, if found in the *Rules of Practice in Patent Cases* may be tied to once-statutory requirements that are no longer a part of the patent law. Others are remnants of practice that sometimes appear in applications but add nothing to the patent drafting effort.

§ 8[a] Differently Worded "Abstract of the Disclosure"

The *Abstract* should not follow *Manual* guidance. Rather, the *Abstract* should strictly mirror, verbatim, the wording used to describe the invention that is found in the claims.

Manual advice should *not* be followed as to abstract draftsmanship as this may lead to a narrowed scope of protection. It is dangerous to rely upon *Manual* because the Federal Circuit may disregard the *Manual* in its interpretation of the regulations and Patent Office Policies. For example, original Rule 72(b) had encouraged applicants to draft an abstract that differed in text from the claims. The rule provided that an abstract "shall not be used for interpreting the scope of the claims[.]"

Yet, the Court in *Hill-Rom* expressly denied this provision:

> "Citing 37 C.F.R. § 1.72(b), which provides that the abstract of the patent 'shall not be used for interpreting the scope of the claims,' Hill-Rom argues that it would be improper for us to consider the abstract in determining whether the district court correctly construed the claims of the '346 patent. Section 1.72(b), however, is a rule of the Patent and Trademark Office that governs the conduct of patent examiners in examining patent applications; it does not address the process by which courts construe claims in infringement actions. We have frequently looked to the abstract to determine the scope of the invention, See, E.g., *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1560 (Fed. Cir. 1997); *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 96 F.3d 1409, 1412 (Fed. Cir. 1996); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1269 (Fed. Cir. 1986), and we are aware of no legal principle that would require us to disregard that potentially helpful source of intrinsic evidence as to the meaning of claims."

Hill-Rom Co. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000)(Bryson, J.); *see also Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 965 n.2 (Fed. Cir. 2000)(citing *Hill-Rom Co. v. Kinetic Concepts,*

Inc., 209 F.3d 1337, 1341 n.* (Fed. Cir. 2000))("[I]n determining the scope of a claim, the abstract of a patent is a potentially useful source of intrinsic evidence as to the meaning of a disputed claim term.")

If the *Abstract* gives a different meaning to claim terminology it may be used to interpret the claims against the interests of the applicant.

§8[b] Background of the Invention

This section is *not* required by statute and should *not* appear in a routine first filing, while there may be basis for *careful* usage of an *Abstract* in a downstream, continuing application. Under Rule 77(b)(5), a patent applicant "should" include in the patent specification a "[b]ackground of the invention". 37 CFR § 1.77(b)(5).

The Patent Office as part of Rule 77(b)(5), while saying there "should" be a *Background of the Invention* never says *what the content should be.*

Thus, there is nothing in the Rules that specify *what* must or should be included in the *Background.* Some guidance is provided in the *Manual of Patent Examining Procedure* which provides for a three part "Background of the Invention". It provides separate areas that should be included.

Per the *Manual*, the Background of the Invention ordinarily comprises two parts:

"(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions. The statement should be directed to the subject matter of the claimed invention.

"(2) Description of the related art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A paragraph(s) describing to the extent practical the state of the prior art or other information disclosed known to the applicant, including references to specific prior art or other information where appropriate. Where applicable, the problems involved in the prior art or other information disclosed which are solved by the applicant's invention should be indicated. See also MPEP § 608.01(a), § 608.01(p) and § 707.05(b)."

MPEP § 608.01(c), *Background of the Invention* [MPEP 8th ed. 2004].

§8[b][1] European View of the Background of the Invention

It is well understood by domestic practitioners that a *Background of the Invention* may create patent validity problems for the patentee. *See KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007), and *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc*., 748 F.3d 1354 (Fed. Cir. 2014), discussing the patentability problem created by identifying a "known problem"). In Europe, to the contrary, a *Background of the Invention* section is recommended under the local laws. Paul Cole, a leading comparative writer based in England, contrasts the European and American approaches to *Background of the Invention* draftsmanship:

> Many influential U.S. attorneys, but not all U.S. attorneys, now recommend an anecdotal approach in which the *Background* is of a general nature only, identifies to starting point in the prior art, and identifies no object or technical problem. * * *
>
> On the European view, one of the most important tasks in the *Background* section is to identify and discuss the closest prior art that provides a starting point for comparison with the subject-matter claimed, and possibly the earlier developments in the field of endeavor of the inventor that led up to that starting point. The selected starting point should be identified by a specific patent number, literature reference or other well-defined disclosure, so that the features that are clearly and unambiguously disclosed in that prior art, expressly or implicitly, can be identified.

Paul Cole, FUNDAMETALS OF PATENT DRAFTING, *The Background Section and the Closest Prior Art* 193, 200-201 (CIPA 2006).

§8[b][2] Japanese Requirement to State "Problem" and "Solution"

Under the September 2015 English version of the Japan Patent Office *Examination Guidelines*, at least one technical "problem" should be solved by the invention which problem should be stated in the application. As noted below, however, there are loopholes to this requirement, particularly for chemical inventions.

This subject is dealt with in more detail at § 6[c][5] "*Problems", "Objects" and "Advantages" for Japan Priority*, based in part on an analysis by the "Uemura group" comprising Shozo Uemura and his colleagues Fumio Inai, Hironobu Kashihara, Shozo Yamashita & Tamaki Yoshida.

The general requirement for a statement of a technical "problem" is stated as follows:

"It is required in normal cases that at least one technical problem that the claimed invention aims to solve be stated as "the problem to be solved by the invention" in the detailed description of the invention."

EXAMINATION GUIDELINES FOR PATENT AND UTILITY MODEL IN JAPAN, Part II, Chapter 1, Section 2, Ministerial Ordinance Requirement, § b(a), ¶ 1, Problem to be solved by the invention and its *solution*, p. 2 (Provisional Translation)(Japan Patent Office Sept. 2015).

Additionally, "[it is also] required in normal cases that how the problem has been solved by the claimed invention be explained as 'its solution' in the detailed description of the invention." *Id.* ¶ 2.

However, if the "problem to be solved" can be understood by persons skilled in the art, given the overall specification and drawings, then it is unnecessary to state the "problem":

"[But], the 'problem to be solved by the invention' is not required to be explicitly stated in a case where a person skilled in the art can understand it without such an explicit statement, when taking into account the statements of the description and drawings, which include statements of prior art or advantageous effects of the invention, as well as the common general knowledge as of the filing (including a

case where a person skilled in the art could comprehend the problem when considering prior art which falls within the common general knowledge). Also, the statement of the solution of the problem to be solved by the invention does not need to be provided in cases where a person skilled in the art would understand how the problem has been solved by a claimed invention by identifying technical problem in the absence of the explicit statement (for example, in a case where how the invention solved the technical problem can be understood by identifying the claimed invention in view of the statements of the embodiment, etc.)."

Id. §b(b), pp. 2-3.

There is a further set of loopholes to excuse the absence of a statement of the "problem", the last mentioned one excusing the absence of a "problem" for claims to a new chemical compound:

"Further, the technical problem does not need to be explicitly stated in a case where a technical problem is by nature not conceived for the invention such as the following item (i), (ii), etc.

"In addition, when the technical problem is not conceived as mentioned above, how the problem has been solved by the invention (i.e., its solution) is not necessary, either. This is because 'its solution' is only meaningful in connection with the technical problem, and how the technical problem was solved by the invention cannot be identified as long as the very technical problem remains unidentified."

"(i) An invention based on an entirely new conception which is completely different from prior art.

"(ii) An invention which is based on a discovery resulting from trials and errors (e.g., inventions of chemical compounds)."

Id., § b(c), p. 3.

§8[c] Field of the Invention

As noted in the previous section, the first part of the *Manual*-proposed *Background of the Invention* is a discussion of the "field of the invention". This is an anachronistic provision that is designed to help the *classification* clerk or examiner determine the proper *classification* of the application for assignment to the appropriate examining division or group. Thus, under the *Manual,* the "field" portion of the *Background* section is "[a] statement of the field of art to which the invention pertains. This statement may include *a paraphrasing of the applicable U.S. patent classification definitions*." *Id.;* emphasis supplied.

To the extent that the field of the invention identified in an application is "rocket science" does this mean that a worker skilled in the art is someone skilled in "rocket science"? Should this be an *admission* that the invention for *KSR* nonobviousness considerations is in the field of a "rocket scientist"? Assume, *arguendo,* that the patent includes a claim for an invention in both "rocket science" and "hybridomas". If "hybridomas" appear higher in the classification manual than "rocket science", then the "field of the invention" for classification purposes is "hybridomas".

Thus, the "field of the invention" is an annoying feature unique to the American *Rules of Practice in Patent Cases* that has everything to do with arbitrary classification rules and nothing to do with the relevant field of the worker skilled in the art. If anything, beyond creating *KSR* problems, the field of the invention creates another, finite time and expense problem for the applicant. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007). (To the extent that it is *helpful* for the Office in classifying patent applications it would be better to *eliminate* the Field of the Invention section and, instead, provide an *optional* box on the

application filing cover sheet noted as: "Proposed official classification" (if known)".

The writer acknowledges that there are other views on whether the field of the invention should be recited in the application. Professor Joshua Sarnoff explains a contrary view:

[He] emphasize[s] the need for the applicant to explicitly consider what the field of his technology is — as the perspective of the [person having ordinary skill in the art] is supposed to govern construction, the applicant needs to identify and (if helpful) shape the choice of field of technology for construction in the specification (including by providing the equivalent of a definition — an explicit statement of what the applicant thinks the field is). This goes against some views of good prosecution, based on identifying art for the analogous arts test or otherwise making more admissions than needed. [I]t is increasingly important and good drafting practice. [*See* Edward Manzo & Joshua Sarnoff, in Edward Manzo, PATENT CLAIM CONSTRUCTION IN THE FEDERAL CIRCUIT § 0:2 (2015 ed.), (discussing importance of the PHOSITA's (objective) perspective)].

Joshua Sarnoff, Private Communication (May 18, 2015).

§ 8[c][1] Japan Identification of "Technical Field"

It is an explicit regulatory requirement in Japan that the "technical field" of the invention be stated: "It is required in normal cases that at least one technical field to which a claimed invention pertains be stated in the detailed description of the invention as a technical field to which an invention pertains." EXAMINATION GUIDELINES FOR PATENT AND UTILITY MODEL IN JAPAN, Part II, Chapter 1, Section 2, Ministerial Ordinance Requirement, § a, *Technical field to which an invention pertains*, p. 2 (Provisional Translation)(Japan Patent Office Sept. 2015).

There are two exceptions to this requirement.

First, if the technical field is understood without an explicit statement of technical field, then the technical field need not be set forth. *Id.* ("[T]he 'technical field to which an invention pertains' is not required to be explicitly stated if *a person skilled in the art can understand it* without such explicit statements when taking into account the statements of the description and drawings, as well as the common general knowledge as of the filing.")(emphasis added).

Second, the technical field need not be stated in the case of "an entirely new conception[.]" *Id.* ("[But], …in cases where the invention does not pertain to existing technical fields such as an invention developed based on an entirely new conception which is completely different from prior art, it suffices [insofar as the requirement for the technical field to which an invention pertains] that the statement[ ] of the new technical field developed by the invention be provided and an application for such an invention does not need to state the existing technical fields.")

§8 [d] "Essence" of the invention

"Reliance on a finding that a 'novel element', or 'essence' (or 'gist', or 'key') of a structural invention lies in the operation of a specification-described embodiment of the claimed structure would render meaningless the statutory requirement for claiming, 35 U.S.C. Sec. 112[.]" *SRI Intern. v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1128 n.7 (Fed. Cir. 1985)(en banc)(Markey, C.J., joined by P. Newman, J., additional views); *see also Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 949 (Fed. Cir. 1987)(en banc)(Nies, J., additional views)("It is axiomatic under our precedent that one cannot obtain

patent protection for an *inventive concept* or for the *heart* or '*essence'* of an invention or for an achieved result. …")

§8[e] **"Essential" Feature of the Invention**

"In determining obviousness, there is 'no legally recognizable or protected 'essential' [feature]… of the invention" *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961).

§8 [f] "Exact Nature" of the Invention

Even today, more than sixty years since a relevant statutory change, the official *Manual* guidance on how to draft a *Summary of the Invention* quotes the *Rules of Practice in Patent Cases* for the proposition that the "summary of the invention [should indicate] its nature ***, which may include a statement of the object of the invention[.]" MPEP 608.01(d), *Brief Summary of Invention* (quoting 37 C.F.R. 1.73, *Summary of the invention*)(emphasis added).

More completely, the paragraph from which this statement was excerpted reads (with emphasis added):

"A brief summary of the invention indicating its *nature and substance*, which may include a statement of the *object of the invention*, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed."

Nature of the invention?

Substance of the invention?

"Object" of the invention?

The *Manual* further states:

"Since *the purpose* of the brief summary of invention *is to apprise the public*, and more especially those interested in the particular art to which the invention relates, *of the nature of the invention*, the summary should be directed to the specific invention being claimed, in contradistinction to mere generalities which would be equally applicable to numerous preceding patents. That is, the subject matter of the invention should be described in one or more clear, concise sentences or paragraphs. ***

"The brief summary, if properly written to set out t*he exact nature, operation, and purpose of the invention*, will be of material assistance in aiding ready understanding of the patent in future searches. The brief summary should be more than a mere statement of the objects of the invention, which statement is also permissible under 37 CFR 1.73."

MPEP 608.01(d), *Brief Summary of Invention* (emphasis added).

§8[g] "Gist" of the Invention

"In determining obviousness, there is 'no legally recognizable or protected …'gist'… of the invention." *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961); *see also CLS Bank International v. Alice Corp. Pty. Ltd.*, 717 F. 3d 1269 (Fed. Cir. 2013)(en banc)(Rader, C.J., joined by Linn, Moore, O'Malley, JJ., concurring in part and dissenting in part), *aff'd sub nom Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)("It would be improper for the court to ignore [claim] limitations and instead attempt to identify some 'gist' … of the invention. See [*Diamond v. Diehr*, 450 U.S. 175, 188 (1981)] (it is improper to dissect the claims; they must be considered as a whole)"). *See also* the suggestion of 37 CFR § 1.73 that the specification should indicate the "gist" of the invention, which implemented a nineteenth century statutory requirement that was not carried forward in the 1952 Patent Act..

§8[h] "Heart" Feature of the Invention

"In determining obviousness, there is 'no legally recognizable or protected … 'heart' of the invention". *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961); *see also Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1540 (Fed. Cir. 1983)(Markey, C.J.)("[The trial court]'s reference to 'the heart of invention' was here a harmless fall-back to the fruitless search for an inherently amorphous concept that was rendered unnecessary by the statute, 35 U.S.C."); *CLS Bank International v. Alice Corp. Pty. Ltd.*, 717 F. 3d 1269 (Fed. Cir. 2013)(en banc)(Rader, C.J., joined by Linn, Moore, O'Malley, JJ., concurring in part and dissenting in part), *aff'd sub nom Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)("It would be improper for the court to ignore

[claim] limitations and instead attempt to identify some … 'heart' of the invention. See [*Diamond v. Diehr*, 450 U.S. 175, 188 (1981)] (it is improper to dissect the claims; they must be considered as a whole)").

In the context of patent infringement, reference is sometimes made to a particular feature of a combination invention representing the "heart" of the invention. But, where the *combination* is not infringed, that ends the matter. As explained in *Mercoid*:

"That result may not be obviated in the present case by calling the combustion stoker switch the 'heart of the invention' or the 'advance in the art'. The patent is for a combination only. Since none of the separate elements of the combination is claimed as the invention, none of them when dealt with separately is protected by the patent monopoly. *Leeds & Catlin v. Victor Talking Machine Co. (No. 1)*, 213 U.S. 301, 318 (1909). Whether the parts are new or old, the combination is the invention and it is distinct from any of them. See *Schumacher v. Cornell*, 96 U.S. 549, 554 (1877); *Rowell v. Lindsay*, 113 U.S. 97, 101 (1885)."

Mercoid Corp. v. Mid-Continent Investment. Co., 320 U.S. 661, 667-68 (1944)(Douglas, J.)

§ 8[i] "Inventive Concept"

The concept of patentability as keyed to the presence of "invention" or an "inventive concept" that developed in the nineteenth century was *codified* in the 1952 Patent Act as 35 USC §103. As explained by the late Giles Sutherland Rich, "[t]erms like 'inventive application' and 'inventive concept' no longer have any useful place in deciding questions under the 1952 Act[.]" *In re Bergy, 5*96 F.2d 952, 961 (CCPA 1979)(Rich, J.)). Nevertheless, the Supreme Court has resuscitated the term "inventive concept" as a condition for patent-eligibility under 35 USC § 101 in a series of cases, particularly beginning with *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), and subsequent case law. *See* **§** 15[a][2], *Patent Eligibility and Patentability Conflated.*

"[Reference is made] to 'the inventive concept'[.] … That facile focus[ ] resulted in treating the claims at many points as though they read differently from those actually allowed and in suit." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1547 (Fed. Cir. 1983)(Markey, C.J.); *see also*; *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 949 (Fed. Cir. 1987)(en banc)(Nies, J., additional views)(("It is axiomatic under our precedent that one cannot obtain patent protection for an *inventive concept* or for the *heart* or '*essence'* of an invention or for an achieved result. …")

§ 8[j] "Novel Element" of the Invention

"Reliance on a finding that a 'novel element', or 'essence' (or 'gist', or 'key') of a structural invention lies in the operation of a specification-described embodiment of the claimed structure would render meaningless the statutory requirement for claiming, 35 U.S.C. Sec. 112[.]". *SRI Intern. v. Matsushita Elec. Corp. of America,* 775 F.2d 1107, 1128 n.7 (Fed. Cir. 1985)(en banc)(Markey, C.J., joined by P. Newman, J., additional views).

§ 8[k] "Object" of the Invention

Recitation of an "object" should be *avoided* as it is *unnecessary* and can lead to a narrowed interpretation of the patent.

Particularly because there is no statutory requirement for an "object" to be stated, it is curious why so many applicants continue to recite "objects" of their invention. The negative impact for claim interpretation is seen from *Netcraft Corp. v. Ebay, Inc*., 549 F.3d 1394 (Fed. Cir. 2008)(Prost, J.) where the Court gave claims a narrow interpretation based upon a narrow definition of the invention that could be gleaned from the "objects" of the invention. The Court quoted from the specification:

> The *main object of the present invention* is to create a new business opportunity for telephone companies, cable television companies, existing Internet access providers, and companies offering financial services by creating a way for them to offer to their subscribers a method of securely buying and selling goods and services of any value over the Internet.
>
> *Another object of the present invention* is an Internet billing method which is cost effective for transactions having transaction amounts ranging from pennies to a few dollars.

Still another object of the present invention is to provide a secure method of billing commercial transactions over the Internet.

A further object of the present invention is an Internet billing method which is simple to use from both the customer's point of view and that of vendors on the Internet.

Yet another object of the present invention is a billing method which can be used by a large number of existing Internet users without requiring major changes in how the users customarily behave and conduct commercial transactions.

These and other objects of the present invention are achieved by an Internet billing method in accordance with the present invention.

Netcraft v. Ebay, 549 F.3d at 1397-98 (emphasis added).

Particularly damaging from the standpoint of interpretation of the claims is the final paragraph quoted above that states that the "objects of the present invention *are achieved by* an Internet billing method *in accordance with the present invention*." In other words, under an extreme interpretation (which occurred in this case) if an embodiment seemingly within the scope of "claim 1" does not achieve all of the objectives stated in the specification, it is not part of the claimed invention.

It can be agreed that "an applicant may want to consider avoiding any characterizations or disparagements of the prior art in the specification and, more importantly, refrain from 'selling' the invention by overly emphasizing objects, advantages, or purposes of the invention in the specification." Bryan C. Diner, C. Gregory Gramenopoulos & Anthony C. Tridico, *Festo: The Tip of the Iceberg*, LES Benelux Newsletter (December 2002).

§ 8[l] "Operation" of the Invention

There is absolutely no statutory basis for the Patent Office statement that the "operation" of the invention should be indicated. *Patent Office Rule 73 and MPEP 608.01(d)*, quoting MPEP 608.01(d), *Brief Summary of Invention* ("The brief summary, if properly written [ ] set[s] out the … operation… of the invention[.]")

§8[m] "Problems" Faced by the Inventor

Recitation of "problems" faced by the inventor should be avoided.

The patent applicant who provides a "Background of the Invention" identifying a known problem in the art creates a problem under *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007). Admission that there is a known problem in the art invites the Examiner of the application or a court evaluating patent validity to conclude that the admission of the known problem creates a motivation to combine references, thereby rendering a possibly unobvious invention obvious.

As explained in *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc*., 748 F.3d 1354 (Fed. Cir. 2014), if there is a "known problem" this may be the thread to lead to a conclusion of obviousness under *KSR*. Thus, "[i]n *KSR*[, 550 U.S. at 421] , the Court explained that 'obvious to try' [to defeat patentability] may apply when 'there are a finite number of identified, predictable solutions' to a *known problem*. The Court explained that when the path has been identified and 'leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.' *Id*." *Sanofi-Aventis Deutschland*, 748 F.3d at 1360 (emphasis added).

As noted by the Chief Judge of the Federal Circuit, "[w]hen a claimed invention involves a combination of elements, however, any need or problem known in the relevant field of endeavor at the time of invention can provide a reason to combine. See *KSR* [550 U.S. at 420-21]. Moreover, the prior art need not address the exact problem that the patentee sought to resolve. Id." *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, __ F.3d __, ___ (Fed. Cir. 2014)(Prost, C.J.).

Institut Pasteur v. Focarino, 738 F.3d 1337 (Fed. Cir. 2013), points in the same direction:

"When there is a design need or market pressure to *solve a problem* and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Institut Pasteur*, 738 F.3d at 1344(quoting *KSR*, 550 U.S. at 421 (2007)(emphasis added).

In yet another case, the Federal Circuit explained that "our cases emphasize that 'where all of the limitations of the patent were present in the prior art references, and the invention was addressed to a 'known problem,' '***KSR*** . . . compels [a determination of] obviousness.'" *Stone Strong, LLC v. Del Zotto Products of Florida.*, 455 Fed. Appx. 964, 969 (Fed. Cir. 2011)(quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1240 (Fed. Cir. 2010), citing *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 993 (Fed. Cir. 2009)).

In *Schwemberger* the admission in the specification of a known problem was a basis to reach a conclusion of unpatentability:

"The *specification … discloses a known problem* …. [M]odifying Pruitt's staple line configuration in accordance with the configuration disclosed by Schulze is no more than 'the combination of familiar elements according to known methods . . . [with] predictable results.' See *KSR* [*Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007)]; see also *id.* at 421 ('When there is *a design need or market pressure to solve a problem* and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.'). Therefore, the Board correctly determined that claim 9 is obvious over the combination of Pruitt and Schulze." *In re Schwemberger*, 410 Fed. Appx. 298, 304 (Fed. Cir. 2010)(emphasis added)

Japan for many years had a statutory provision that suggested that problems should be recited in the specification. This provision, however, was abolished from the Japanese patent law in 1995.

§8[n] "Purpose" of the Invention

There is no requirement to recite the "purpose" of the invention. Cf. *Patent Office Rule 73 and MPEP 608.01(d)*, quoting MPEP 608.01(d), *Brief Summary of Invention* ("The brief summary, if properly written [ ] set[s] out the … purpose of the invention[.]")

§8[o] "Shorn claims"

"[The brief refers] to the claims 'shorn of their extraneous limitations'. That facile focus[ ] resulted in treating the claims at many points as though they read differently from those actually allowed and in suit." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1547 (Fed. Cir. 1983)(Markey, C.J.).

§8[p] "Substance" of the Invention

In conflict with the advice in § 510, *"Summary of the Invention", a Definitional Section*, the Patent Office says that the "substance" of the invention should be indicated. *See* § 831, *Patent Office Rule 73 and MPEP 608.01(d)*, quoting MPEP 608.01(d), *Brief Summary of Invention* ("[T]he application should include [a] brief summary of the invention indicating its … substance ….")

§8[q] "Thrust" of the Invention

"[W]e note [the patentee's focus on one feature] which it called the 'thrust of the invention'. That approach is repeated throughout [it's] briefs, which refer repeatedly to the 'thrust of the invention'…. That facile focus[ ] resulted in treating the claims at many points as though they read differently from those actually allowed and in suit." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1547 (Fed. Cir. 1983)(Markey, C.J.).

§ 8[r] "Advance in the Art"

A particular feature within a combination claim may be characterized as an "advance in the art", but unless the combination is practiced, there is no infringement of that "advance in the art". *See Mercoid Corp. v. Mid-Continent Investment. Co.*, 320 U.S. 661, 667-68 (1944)(Douglas, J.).

♦ ♦ ♦

§ 9. "Cook Book" Text of the Preferred Embodiment

At the start of the drafting process, the sophisticated applicant should be able to provide much if not all of predicate information to the practitioner necessary to draft the patent application. Whether the purpose of the application is offensive or defensive, it is important to have a detailed example of the invention for the *Detailed Description of the Invention.* The inventor stands in the best position to provide either a "cook book" recipe with all the details of the invention or a "blue print" disclosure of the preferred embodiment including reference numerals to a code identifying the elements.

For the exceptional case in the area of unpredictable technologies where an "upstream" application is drafted to generically cover yet to be created "downstream" embodiments, the inventor once again is in the best position to provide a set of plural, representative prophetic embodiments to support generic protection. It is not enough that it is "obvious" how to make the various embodiments; the important point is that they are *disclosed* in the application.

Prior art information should be provided by the inventor for the practitioner. As a bare minimum, the inventor should identify his "starting off" point:

What is the point of departure from the prior art that led to his invention?

A useful starting point for the patenting process is for the inventor to provide the patent attorney with an electronic (Word) copy of the best example in the form of a "cook book" recipe.

This information provides a critical component to understanding the invention before conducting a search or before preparing the patent application is a complete understanding of the various aspects of the invention. Only when the concrete embodiment of the invention is known to the patent attorney then and only then can the full parameters be known of what *can* be patented.

The "cook book" example also provides the "guts" of the patent application and will find its way into "Example 1" of the patent application.

If, on the one hand, the only business objective is a purely *defensive* right to block a junior inventor from obtaining a patent right to dominate a specific, commercial embodiment, then the answer may be "yes" – an applicant should be able to file a provisional application as long as the applicant understands that the provisional application should

Just as a kitchen recipe has the most minute details as to how to prepare a dish the patent "cook book" example should go into the same excruciating detail, leaving no stone unturned. The "cook book" example should show the complete construction of the commercial embodiment with every detail.

§ 9[a] Plural Embodiments for Broad Defensive Protection

It is helpful but not absolutely always unnecessary for the purposes of drafting a first application to have plural embodiments provided by the inventor. For example, if the only concern of the applicant is *defensive* and that concern extends only to a specific product, then a disclosure of that specific product will be sufficient to create defensive rights against junior applicants.

However, this is a simple case that does not usually comport with the real world. Even for a defensive patenting situation, the applicant may wish to keep the door open to obvious or even further remote variations of his current embodiment. To best accomplish this, specific examples to cover such obvious or even further removed subject matter should be prepared, *but not at the expense of holding up the filing date.* (If plural embodiments are important, then one option is to immediate file a provisional application with the one embodiment, and then as soon as possible file a *second* application covering the plural embodiments.)

At first blush, one may think that having broad claims would suffice to provide the necessary breadth of defensive protection. However, gaining a broad claim only provides the applicant with broad coverage but does not necessarily provide a basis for anticipation of a competitor's claim reading on the new embodiment.

§ 9[b] Specific (versus Generic) Defensive Disclosure

If the applicant's specific working example is in a large generic field that specific working example is unlikely to block a *subgeneric* claim to a fairly large group of embodiments *unless* there is a *specific disclosure* in the prior art of a member of the subgeneric claim. A set of plural *specific* embodiments should be set forth in the specification so that each subgeneric area of interest is anticipated by a specific disclosure.

There is a school of thought that a broad *claim* or disclosure provides optimum patent-defeating effect against a junior claim within the scope of that disclosure. This is not generally the situation. Thus, it is whether the prior art *describes* a claimed invention that is critical to patentability of the claimed invention and not whether the claimed invention is within the scope of the generic disclosure. Indeed, if the claim is very broad it merely defines the periphery of the scope of protection and does not describe the embodiments within its scope: "[C]laims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed which define the area conveyed but *do not describe the land*." *In re Vamco Machine and Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985)(Rich, J.)(emphasis added).

In other words, "a patent may be thought of as a form of deed which sets out the metes and bounds of the property the inventor owns for the term and puts the world on notice to avoid trespass or to enable one to purchase all or part of the property right it represents." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 997 (Fed. Cir. 1995)(Mayer, J., concurring), *aff'd*, 517 U.S. 370 (1996). "The legal effect of the patent claim is to establish the metes and bounds of the patent right to exclude[.]" *Markman*, 52 F.3d at 1000(Newman, J., dissenting).

To be sure, there has been some leniency in reaching a conclusion of anticipation where there is only a general description of the embodiment. As explained by Circuit Judge Linn in Kennametal the test for anticipation with only a generic recitation of the ingredients – not showing the specific combination to anticipate – is satisfied if the worker skilled in the art, given the generic recitation, "would 'at once envisage' the claimed arrangement[.]" *Kennametal, Inc. v. Ingersolling Cutting Tool Co*., __ F.3d __, __ (Fed. Cir. 2015)(Linn, J.)(quoting *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962)("[A] reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination."

§ 9[c] Prophetic, Patent-Defeating Examples

The case law makes it clear that a reference that has an enabling disclosure may constitute an anticipation of a claim even where the reference disclosure had not been actually carried out, i.e., there was no "actual performance" of the invention in the prior art. As explained by Circuit Judge Linn: "Though it is true that there is no evidence in [the prior art reference] of 'actual performance' of [the invention], this is not required." *Kennametal, Inc. v. Ingersolling Cutting Tool Co.*, __ F.3d __, ___ (Fed. Cir. 2015)(Linn, J.)(quoting *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005), quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001)).

As explained in *Kennametal*, for a prophetic example in the prior art to constitute anticipation, "anticipation only requires that [the disclosure] be enabled to one of skill in the art." *Kennametal, Inc. v. Ingersolling Cutting Tool Co.*, __ F.3d __, __ (Fed. Cir. 2015)(Linn, J.)(quoting *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005), quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001)).

§ 9[d] Prophetic Examples should be Stated in the Present Tense

Prophetic examples which include aspects of the example which have not been worked out in the laboratory should be stated in the *present tense* so that there is no representation that experiments have been carried out.

§ 9[e] **"How to Use" (for Biotech and Chemical Inventions)**

If the invention involves a new chemical or biotechnology entity in an unpredictable art area of pharmaceuticals it is important to include with the "cook book" example the method of use. Even if the invention is a pharmaceutical candidate where there has been no human testing, if there is *in vivo* data available it is useful to include this information as an adjunct to the "cook book" example. .

§ 9[f] Inventor Guidance to Draft the "Cook Book" Example

Inventors are generally given *theoretical* advice on the disclosure needed for an application, whether as a "cook book" example or otherwise. As a practical matter, the instructions are largely theoretical and of little practical guidance because they lack real world reality for the technology involved.

It is suggested that for specific areas of research that the effort be made to identify, say, five recent patents drafted by quality corporate patent departments or law firms *in the exact area of technology of the specific area of research.* Then, the enabled embodiment should be highlighted in yellow, as should the generic claims. This will provide the inventors with *practical* guidance as to how to draft an enabled embodiment.

§10. Prior Art

§ 10[a] Prior Art Information as a Predicate to Claim Drafting

Prior art information is important for offensive patent purposes where claims of appropriate scope are to be obtained.

In limited situations where offensive protection is to be sought, a search may well be postponed. For example, some practitioners are ready to draft an application based merely upon the disclosure of the inventor's best embodiment. For example, in a corporate environment where a particular practitioner as part of his daily work covers a very narrow area of technology with the same set of inventors, here, it is possible that the practitioner will have a good feel for the state of the art – or can update his understanding with his own brief electronic search – so that he may proceed with the drafting of the original application even without a patentability search.

Usually, however, the practitioner needs the cooperation and help of the inventor to determine the state of the art as a predicate to drafting the patent claims.

§ 10[a][1] An Informed Patentability Search

Is a "patent search" necessary before filing? What is meant, more precisely, is the question whether a *patentability* search is needed. *See* § 233, *The Various Traditional Searches* (discussing the several different types of searches for patent purposes). If the first filing is a provisional application, there is never a need to cite prior art to the Examiner during the pendency of the provisional application.

The search should be an "informed" search where the searcher is given the inventor's information about his "starting off" point.

If the invention is an improvement in an existing product it may be enough to identify this "starting off" point for the purpose of filing a provisional application. If the *only* purpose of the filing is defensive then certainly no further patent search is required: The patent-defeating effect sought for the defensive patent right is *automatically* achieved 18 months from the effective filing date when the application is published, thereby creating a patent-defeating effect against both novelty under 35 USC § 102 and nonobviousness under 35 USC § 103 which is retroactive to the filing date.

Even for an offensive patent right, it may be sufficient for purposes of a provisional application to rely upon the "starting off" point information so that the earliest filing date can be achieved that is so essential in a first-to-file world. Then, the invention should be kept secret while any patent search that is necessary is conducted – and there is time for a second filing to take this information into account.

A "patentability search" to determine whether an invention is patentable is useful but should not hold up the initial filing of a provisional application, if the inventor has given the patent attorney "starting off" point for his invention. The goal of the first filing is to *promptly* file an application.

A major reason to have a full knowledge of the state of the art is to be able to pinpoint the feature of the invention that most readily distinguishes the invention from the prior art. In this way, claims can be focused upon a single inventive feature: Claims can then be crafted so that all other elements are optional, providing the broadest possible protection.

More traditional thinking – that may indeed represent the majority view – is that a patent search should always be done so that resources are not put into an invention where no patent will be granted:

Doing a patent search is absolutely essential. Until you understand what is already known in the prior art you have absolutely no way of knowing whether a patent is likely to be obtained. Furthermore, without a thorough and complete picture of the prior art you are unable to focus the description of your invention on those aspects that will most likely contribute to patentability. Without a patent search you will invariably describe all aspects of the invention with equal importance, although … there will always be certain features that deserve greater attention because they will contribute more to patentability. While it is helpful to identify any difference between an invention in the prior art, it is critical to spend the greatest amount of time discussing the features and variations that that will contribute to a patent being issued; that is where the patentable invention resides. This uniqueness will allow you to build a patent application that can lead not only to a patent, but a patent that meaningfully protects the core of what makes the invention unique compared with the prior art.

Gene Quinn, *Patent Drafting: Identifying the Patentable Feature*, IPWatchdog.com (January 17, 2015).

§ 10[a][2] Inventor's "Starting Off" Point, the State of the Art

The inventor should inform the patent attorney of the closest prior art, usually the "starting off" point for the invention.

Generally, the applicant has such a starting off point for his invention, some commercial or other prior art disclosure that is basis for his improvement. The searcher should be armed with the best prior art known to the applicant which forms the starting off point for the search:

Here, the searcher will then *skip* at first seemingly relevant prior art but which is *less relevant* than the applicant's own starting point knowledge. Thus, whereas a searcher starting from scratch may pull, say, thirty or forty references as seemingly pertinent, if the searcher starts with a truly pertinent prior art reference supplied by the applicant, then it is possible that he will find *nothing* as or more pertinent that the starting point prior art. But, at most, the total number of prior art references will be far, far less than the situation where the searcher has no starting off point for his search.

There are plural benefits to providing the searcher with the applicant's best known prior art:

First of all, the search will be *better* because now the searcher can focus on finding only those references as or more pertinent than what the applicant has provided.

Second, the search results will be far more manageable than where the searcher starts from scratch. If the searcher armed with the applicant's best prior art comes up with, say, only five prior art references, then all five references (plus the applicant's own citation) will be manageable and easily useful to the Examiner.

But, if there are, say, fifty prior art references where the searcher did not have a starting off point, citation of all fifty references will at best obfuscate the serach results and be far less valuable to the examiner.

§ 10[a][3] **Avoiding a "Willfully Blind" Search**

Any prior art search should start with the inventor's own starting off point or other close prior art known by the inventor**.**

Some may wish to have a search conducted *without* the starting off point of the closest known prior art: If no starting off point is given to the searcher, then maybe the searcher *won't find the best prior art* and the application may be allowed because the best prior art was not cited. This is a totally flawed strategy: First of all, the duty of disclosure runs to what the applicant knows: Hiding the ball from the searcher doesn't change this fact.

Secondly, hiding the prior art from the searcher so he doesn't find the best prior art on his own will hardly help the applicant. By analogy consider the situation where knowledge of a competitor's patent is a predicate to active inducement under 35 USC § 271(b). In the *T-Fal Fryer* case, *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (Fed. Cir. 2010)(Rader, J.), an overseas competitor bought the commercially popular kitchen utensil which it copied without actual knowledge of the existence of the patent. In order to establish good faith, the competitor commissioned an infringement search where he gave the searcher a description of the utensil *but failed to inform the searcher of the identity or existence of the commercial product.* The Courts conceded that the competitor lacked actual knowledge, but considered the failure to provide the searcher with the knowledge of the existence of the copied product equivalent to actual knowledge, either under a theory of "deliberate indifference" as found by the

Federal Circuit in *SEB v. Montgomery Ward*, or -- as modified by the Supreme Court on appeal – "willful blindness", *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

The obfuscation was unsuccessful:

"[A] claim for inducement is viable even where the patentee has not produced direct evidence that the accused infringer actually knew of the patent-in-suit. This case shows such an instance. The record contains adequate evidence to support a conclusion that [the accused infringer] deliberately disregarded a known risk that SEB had a protective patent. The jury heard evidence that that [the accused infringer] purchased an SEB deep fryer in Hong Kong and copied all but the cosmetics. The owner of a company related to that [the accused infringer] testified that that [the accused infringer]'s engineer took a T-Fal deep fryer and used 'the same ring that separates . . . the wall making it a cool touch unit and the construction, basically everything the same; thermostat, it was the same; the timer was the same, just a little bit different on the cosmetics of the outside appearance for the deep fryer.' Again, the record shows that [the accused infringer] hired an attorney to conduct a right-to-use study, but did not tell him that it had based its product on SEB's product.

A failure to inform one's counsel of copying would be highly suggestive of deliberate indifference in most circumstances. Here, the jury also heard testimony that indicated that that [the accused infringer]'s president, John Sham, was well versed in the U.S. patent system and understood SEB to be cognizant of patent rights as well. Sham testified that he was the named inventor on 29 U.S. patents and that that [the accused infringer] and SEB had an earlier business relationship that involved one of that [the accused infringer]'s patented steamer products. The record thus contains considerable evidence of deliberate indifference [as the equivalent of actual knowledge of the patent].

SEB v. Montgomery Ward, 594 F.3d at 1377.

§ 10[a][4] The Various Traditional Searches

For purposes of patent drafting, the traditional search is the "patentability search" where the sole object is to determine whether an invention is new and nonobvious.

Other searches include the "infringement search" and the "validity search".

The infringement search determine whether the invention may be practiced without infringing a third party's patent. There is no issue, *here*, whether the invention itself is patentable.

The "validity search" determines patentability issues but in the context as to whether a current patent is valid. Based upon the amount of money at stake and whether the accused infringer may face an injunction shutting down his business the scope of the validity search may be quite extensive and have a virtually unlimited budget to cover searching far beyond classified patents.

§ 10[b] Citation of Prior Art

In a first filing, it is important to *cite* the prior art but not to *characterize* that prior art or otherwise argue patentability at this early stage of the process. Prior art should as a default never be cited in a first filing, but prior art should be *identified* in a separate Information Disclosure Statement.

§ 10[b][1] Citation, not Characterization, of the Prior Art

It is best to *cite* but not characterize the prior art both from the standpoint of the initial review of the case by the Examiner as well as for the long range consequences of how the claims will be interpreted in a post grant proceeding or litigation.

The last thing that an applicant should want for the initial first impression of the Examiner is an *argument* between applicant and Examiner. But, this is *precisely* what is invited where the citation of prior art includes the applicant's *characterization* of the prior art – whether that occurs in an Information Disclosure Statement, a specification discussion of the prior art – or both. Instead, the Examiner will surely *welcome* the simple citation of the closest prior art as part of two or three citations: The Examiner then has the opportunity to conduct his *own* search to see whether he finds anything better, and, if not, to objectively view the prior art from his own perspective *without argumentation.*

§ 10[b][2] Citation distinguished from Characterization

There clearly is no requirement to make an argument against the prior art: It is the task of the Examiner at the outset to make a determination whether the claimed invention is patentable versus the cited prior art.

PTO regulations make it clear that there is no such duty to *characterize* the prior art: For English language prior art, all that is required is "[a] list" of the prior art; foreign language prior art requires "[a] concise explanation of the relevance.":

37 CFR § 1.98 Content of information disclosure statement.

"(a) Any information disclosure statement filed under § 1.97 shall include the items listed in paragraphs (a)(1), (a)(2) and (a)(3) of this section.

"(1) A list of all patents, publications, applications, or other information submitted for consideration by the Office. U.S. patents and U.S. patent application publications must be listed in a section separately from citations of other documents. Each page of the list must include:

"(i) The application number of the application in which the information disclosure statement is being submitted;

"(ii) A column that provides a space, next to each document to be considered, for the examiner's initials; and

"(iii) A heading that clearly indicates that the list is an information disclosure statement.

"(2) A legible copy of:

"(i) Each foreign patent;

"(ii) Each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office;

"(iii) For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and

"(iv) All other information or that portion which caused it to be listed.

"(3)(i) A concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein.

"(ii) A copy of the translation if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, custody, or control of, or is readily available to any individual designated in § 1.56(c).

"(b)(1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.

"(2) Each U.S. patent application publication listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.

"(3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.

"(4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office

which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.
"(5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.
"(c) When the disclosures of two or more patents or publications listed in an information disclosure statement are substantively cumulative, a copy of one of the patents or publications as specified in paragraph (a) of this section may be submitted without copies of the other patents or publications, provided that it is stated that these other patents or publications are cumulative.
"(d) A copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless:
"(1) The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120; and
"(2) The information disclosure statement submitted in the earlier application complies with paragraphs (a) through (c) of this section."

§ 10[b][3] Avoiding any *admission* of Prior Art Status

If there is any doubt whatsoever whether a reference is or is not "prior art", then such a reference *should* as a matter of best practices be cited to the PTO in an Information Disclosure Statement. But, it is best to cite the reference *without* an admission that the reference is prior art; the facts as known to the applicant should be provided to the Examiner to permit him or her to make the necessary determination.

Even *if* a mistake is made and an *admission* of prior art status is erroneously made, it may be possible to correct this situation and revoke the admission, particularly if the work described was the applicant's own work: "One's own work may not be considered prior art in the absence of a statutory basis, and a patentee

should not be 'punished' for being as inclusive as possible and referencing his own work in an IDS." *Riverwood Intern. Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003)(Linn, J.).

Citing *Riverwood*, it was held in *Abbott v. Baxter* that the "mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art." *Riverwood Intern. Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003)(Linn, J.).

Yet, in the context of a less sympathetic appellate panel, it is possible that a prior art admission would stick and be basis for an affirmance as happened in *Tyler Refrigeration v. Kysor Indus. Corp*., 777 F.2d 687 (Fed. Cir. 1985)(Davis, J.). In that case the Court stated:

"We *** have before us the issue of whether the Aokage patent was prior art within the meaning of 35 U.S.C. § 102. The district court decided on two separate and independent grounds that the Aokage patent was such prior art. One basis was Tyler's admission of the Aokage reference as prior art before the PTO during the prosecution of the [ ] Subera patent. The court found that, in a wrap-up amendment, the Tyler attorney admitted in his discussion as to 'all the claims' of the three Subera applications, that '[t]he most pertinent available *prior art* known to the Applicants and their representatives is the Aokage U.S. Patent 4,026,121 cited by the Examiner' (emphasis added [by the court]). In view of this explicit admission, the district court's decision was proper and was sufficiently based on clear and convincing evidence.

The controlling case law in this court recognizes this principle. *See Aktiebolaget Karlstads Mekanisk Werstad v. ITC,* 705 F.2d 1565, 1574 (Fed.Cir.1983); *In re Fout*, 675 F.2d 297, 300 (CCPA 1982), and *In re Nomiya,* 509 F.2d 566, 571 (CCPA 1975). Thus, we must affirm the court's decision that the Aokage patent was prior art and as such binding on Tyler."

Tyler Refrigeration , 777 F.2d at 690.

Assuming that the claims are eventually allowed where there *has* been argumentation in the Information Disclosure Statement or the prosecution history, this argumentation could come back to haunt the patentee to the extent that the argument points to a different claim construction than stated in the claims, *or* the prosecution history establishes a basis for motivation to make the invention under *KSR* – or both.

§ 10[b][4] Information Disclosure Statement (IDS)

§ 10[b][4][A] The Duty to Disclose under Rule 56

The applicant *must* cite the best prior art known to the applicant at the time of filing (supplemented by later updated information as long as the patent application remains pending).

§ 10[b][4][B] "Information" Important to the Examiner

§ 10[b][4][C] Content of an Information Disclosure Statement

Patent applicants have "a duty to disclose to the Office all *information* known to that individual to be *material* to patentability ***." 37 CFR §. 1.56(a), Duty to disclose information material to patentability (emphasis added).

The full subsection (a) states that:

"A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
(1) prior art cited in search reports of a foreign patent office in a counterpart application, and
(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office."

"Information" is deemed "material" if it is not already known to the PTO and if it either "establishes ***a prima facie case of unpatentability of a claim" or "refutes, or is inconsistent with, a position the applicant takes" in an argument against the PTO or in making a positive argument of patentability. 37 CFR § 1.56(b)("Under [37 CFR § 1.56(a)], information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.")

A case of "prima facie [ ] unpatentability is deemed to be "established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." 37 CFR §. 1.56(b).

§ § 10[b][4][D] Form of Submission

There is no requirement to cite the prior art in the specification. Rather, it may be filed as part of an Information Disclosure Statement under 37 CFR § 1.97 :

"37 CFR § 1.97 Filing of information disclosure statement.

"(a) In order for an applicant for a patent or for a reissue of a patent to have an information disclosure statement in compliance with § 1.98 considered by the Office during the pendency of the application, the information disclosure statement must satisfy one of paragraphs (b), (c), or (d) of this section.

"(b) An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

"(1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

"(2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

"(3) Before the mailing of a first Office action on the merits; or

"(4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

"(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:
"(1) The statement specified in paragraph (e) of this section; or
"(2) The fee set forth in § 1.17(p).
"(d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:
"(1) The statement specified in paragraph (e) of this section; and
"(2) The fee set forth in § 1.17(p).
"(e) A statement under this section must state either:
"(1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
"(2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.
"(f) No extensions of time for filing an information disclosure statement are permitted under § 1.136. If a bona fide attempt is made to comply with § 1.98, but part of the required content is inadvertently omitted, additional time may be given to enable full compliance.
"(g) An information disclosure statement filed in accordance with this section shall not be construed as a representation that a search has been made.
"(h) The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).
"(i) If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office."

The Patent Office is helped when there is a focused citation of the most relevant prior art. The Patent Office has made it clear that the citation of "cumulative" or "marginally relevant documents" is *not* helpful.

§ 10[b][5] "[M]arginally relevant documents" should not be Cited

"[A]pplicants and practitioners mistakenly believe that [they] must submit questionably or marginally relevant documents in order to ensure compliance with the § 1.56 duty of disclosure. A limited amount of time is available for an examiner's initial examination of the application…. [*T*]*he situation is worsened when a large number of the documents are* irrelevant, marginally relevant, or *cumulative*." *Changes to Information Disclosure Statement Requirements and Other Related Matters* (Proposed Rulemaking), 71 FR 38808, 38809 (2006)(emphasis added)

§ 10[b][6] "Cumulative" Prior Art Should not be cited

Prior art that is merely cumulative to, or less relevant than, information already of record should not be cited: "[I]nformation is material to patentability when *it is not cumulative* to information already of record or being made of record in the application…" 37 CFR § 1.56(b)(1) (emphasis added) "*A cumulative reference… is not material*" under the duty of disclosure. *Taltech Ltd. v. Esquel Enters.*, 604 F.3d 1324, 1329 (Fed. Cir. 2010)(dictum)(citing 37 C.F.R. § 1.56(b))(emphasis added).

♦ ♦ ♦ ♦

PART (III): THE CLAIMS, THE CENTRAL FOCUS

§ 11. A Holistic, Claims-Focused Presentation

The applicant is able to freely choose a claim that he thinks best defines the subject matter he wishes to patent. As explained by the Acting Chief Judge, "[w]hile the examiner states the requirement to be claims which 'particularly point out and distinctly claim *the invention'* [ ], § 112 actually requires claims 'particularly pointing out and distinctly claiming *the subject matter which applicant regards as his invention'* [ ]. In reality, this means that applicant must particularly point out and distinctly claim the subject matter sought to be patented." *In re Borkowski*,, 422 F.2d 904, 909 (CCPA 1970)(Rich, Act'g C.J.)(emphasis added by the Court).

§ 11[a] Simplicity as a Necessary Strategy Component

The drafting goal should be to present an application that is simple easy to read – for the Examiner, a prospective licensee or the judge in an infringement proceeding. It is in the first instance of extreme importance that the applicant present a simple set of claims and supporting specification that is easy to examine so that there will be a complete ex1amination in short order without RCE's or other refilings – and without the accompanying baggage of extensive prosecution history.

Where the patent application reaches the desk of the Examiner that is muddled with too many claims, too many references and insufficient, focused argumentation, the application is unlikely to receive favorable consideration. Furthermore, while some applications receive a supervisory review as in the case

of issues of patent-eligibility under Section 101 in light of cases such as *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014), if the case is muddied the review may be delayed for months… many months. The current Vice-Chair of the Patent Public Advisory Committee has expressed this common complaint of the patent community:

"[E]xaminers are expressing to [patent practitioners] … that they don't have proper guidance [on Section 101 patent-eligibility issues] because they do not have proper direction within their art unit. From their directors and among other examiners there is conflict. So when I hear [the Office leadership] say … is that you're going to spend [supervisory time] reviewing them, looking at them, but then that sends client's applications months and months down the pike of having nothing done on them. And then considering whether to suspend prosecution just because we can't get a good answer out of the Office, this is a large concern for clients."

Patent Public Advisory Committee Meeting, Alexandria, Va., August 14, 2014, pp. 24-25 (Remarks of the PPAC Member, Marylee Jenkins), available at http://www.uspto.gov/about/advisory/ppac/ppac_transcript_20140814.pdf (last visited May 18, 2015).

§ 11[a][1] Simple Claims and Straight-Forward Supporting Disclosure

While an applicant has the right to submit an unlimited number of claims, a right to submit a seemingly infinite number of prior art references and a right to include numerous non-statutory sections such as "objects", "problems", *Background of the Invention* and so forth, when the applicant takes advantage of each "right", collectively consider the contrasting picture of a "simple" application versus one where the "rights" are used in the extreme:

The "simple" application is filed with seven or eight claims, a voluntary citation of five or six references and the specification is broken down into (a) a Summary of the Invention (including all definitions necessary to define the

invention over the prior art, a statement of utility (for biotechnology and chemical cases); (b) Brief Description of the Drawings; and (c) a Detailed Description of the Invention (a "thick" section important for interpretation of and support of the claims but unnecessary for the examination). (And, of course, there is an Abstract of the Disclosure).

The "rights" application is filed with seventy or eighty claims (instead of the seven or eight claims in the "simple" application, fifty or sixty prior art references (instead of the five or six citations in a "simple" application) and lengthy specification including a Background of the Invention, "problems", "advantages" and "objects" without segregation of elements necessary for examination (in contrast to the "simple" application with all information necessary for examination segregated into a Summary of the Invention and without the non-statutory elements).

The "simple" application presents a compact picture of the invention and the prior art and, with few claims, permits the examiner to make a thorough examination on the merits of all formal issues under Section 112 as well as a complete examination for novelty and nonobviousness. The Examiner in the limited time for examination of each case does have enough time to find and point out all apparent issues under both Section 112 as well as the classic patentability issues. The applicant thus has a chance to either amend the claims to overcome real defects or, if the defect is only apparent and not real, point out why the claims present a clear and supported picture of the invention, creating a solid prosecution history best suited to defend the patent in a Post Grant Review.

The "rights" application cannot possibly lead to a quick resolution because there are simply too many claims and too many potential issues with so much prior

art. The chance for contradictory positions by the applicant looms large where it is difficult to square the "problems" and "objects" with the literal scope of the claims. The likely first action by the Examiner will be a rejection under Section 103 based upon a combination of several references presenting a sufficient basis to deny allowance of an application where there simply has not been enough time for a complete examination on the merits. Refiling as an RCE or otherwise is inevitable. A messy prosecution history will be the result, a perfect formalities piñata for a Post Grant Review attack.

§ 11[a][2] A Simple Presentation Easy for the Examiner to Digest

This book proposes a simple presentation of an invention with a minimum number of claims, a focus on a complementary disclosure in support of such claims without nonstatutory elements such as a Background of the Invention or "problems" that obfuscate the invention and citation of only the most relevant prior art. Simple presentation is the best guarantee that the Examiner will quickly be able to conduct a thorough examination on the merits – an implicit condition precedent to allowing the application at an early stage (as opposed to kicking the can down the road by maintaining an rejection based upon a sometimes incomprehensible combination of many references that will then provoke an RCE or other refiling).

While one focus is on presentation of a minimal set of claims, all necessary claims must be included. But, to properly decide what is necessary, one must precede the drafting process with an analysis of the business objectives of the applicant. In some situations, offensive coverage is irrelevant so that any set of claims will suffice. At the opposite extreme, a carefully layered set of claims of diminishing scope will be needed to best safeguard offensive rights.

It should also be noted that a minimalist claiming approach does not necessarily mean narrow protection. To the contrary, a claim to the minimum number of elements where elements at the point of novelty are generalized with inclusion of equivalents will provide far broader protection than where an invention with ten elements or steps results in several dozen claims covering every combination and permutation of subcombinations but without the point of novelty approach for generic protection.

Part of the task of the patent draftsman is to make examination easy for the Examiner. Complementing the presentation of a minimal number of claims, the "meat" of the specification necessary for examination should be bundled in a relatively brief Summary of the Invention, an opening section containing all information needed by the examiner including a verbatim recitation of the elements of the invention corresponding to the claims, a definitional section for key terms that need interpretation and little else.

Of particular importance is that the Summary of the Invention be focused upon a repetition of the statement of the invention keyed to verbatim wording usage in the claims, coupled with definitions. What should not be included are nonstatutory elements of no help to sustaining validity but which, at best, are argumentative and at worst are basis for arguments for invalidity or for a narrow construction. Above all, no Background of the Invention, "objects", "problems" or "advantages" need nor generally should be included.

Following the Summary of the Invention should follow a much thicker Detailed Description of the Invention which contains as many examples as

possible: This information is useful in court to construe granted claims, but (apart from chemistry and biotechnology) unnecessary for consideration by the Examiner.

This book is focused upon the first filing of the patent application in a normal situation where an invention is of very recent vintage and where there are many unknowns: What is the complete state of the prior art, given particularly that there are up to eighteen months of previously filed patent applications yet to be published but which upon publication are retroactively prior art as of the effective filing date? What is the true scope of protection that is needed? Is the full generic scope of "claim 1" required? The answers may be available only years after filing. What unobvious properties are possessed by the invention? In some instances as in pharmaceuticals comparative test results with the prior art may not be known for some time.

Finally, no prior art should be cited in the specification. To be sure, within three months of filing, the applicant should submit an Information Disclosure Statement (the IDS) that identifies the best known prior art. The IDS should cite the two or three most relevant prior art references and not the eighty or ninety references found in a search. Obfuscation with irrelevant prior art only adds an unnecessary burden on the examiner's time which is hardly in the interests of the applicant. (If the two or three best references cannot be pinpointed out of the eighty or ninety references found in the search, surely all but five or ten can be culled out as less relevant references.)

§ 11[a][3] A Clearer Downstream Picture Later in Prosecution

The proposal for a simple presentation is of course subject to modification as time goes by. For example, an immediate need for grant of a specific claim may be needed for licensing or litigation. Here, the applicant may negotiate with the examiner to narrow the claim coverage to any degree as long as the commercial species is included in the grant.

Or, if necessary, the applicant may wish to take a patent only on the specific embodiment, while filing a "Vogel trailer" continuing application to cover the remaining subject matter. (A "Vogel Trailer" is a continuation patent with a generic claim overlapping that of a first patent. *See* Panel discussion, *The End of Equivalents? Examining the Fallout From Festo,* 13 Fordham Intell. Prop. Media & Ent. L.J. 727, 742 (2003) (discussing the "Vogel Trailer" and implications of *In re Vogel*, 422 F.2d 438 (CCPA 1970), where the prior patent was to a method of treating "pork" whereas the later case was to the same method for treating "meat".) Or, a new attorney may come fresh to take over a bogged down procurement with multiple RCE's and a history of more than five years of filing.

The obvious solution for a fresh approach is a continuation application (as opposed to an RCE), as the continuation application will have a brand new, fresh electronic file wrapper devoid of the perhaps dozens of papers in the earlier prosecution. Here, at this time, the business objectives are more finely honed and the state of the prior art is also more fully developed. In such a case, one may wish to consider adding a section explaining the prior art. Additional disclosure bolstering the nonobviousness case may also be included.

While care should be taken to avoid new matter that would deny reliance upon the parent filing date, some additions can be made, including a second utility

that distinguishes over the prior art: Even though that utility is not disclosed in the parent, such a "second utility" is not needed for priority.

Application drafting should be simple and straightforward. The best application will have as many claims as necessary to cover business interests but with no further claims. That an applicant can file up to twenty claims for the minimum claims fee should not be an invitation to file twenty (or more) claims: If five or six claims satisfy the business interests that is sufficient.

A minimum number of prior art references should be cited. If the searcher provides, say, eighty references and all but five can be ruled out as secondary or merely cumulative, then just the five references should be cited.

Above all, applicants must simplify prosecution with few claims, citation of few references and a clean prosecution based upon careful notes about claims support. In theory, a patent to a combination of, say, seven elements that has eighty claims directed to every combination, subcombination and permutation of may provide better protection than a patent with nine claims.

But, if a carefully drafted patent has just three or four generic and subgeneric claims focused on critical elements and subcombinations at the point of novelty such claims will provide broader protection than the eighty claims that have not focused on the point of novelty. The carefully drafted application with few claims is more likely to be free from ambiguities while any apparent ambiguities will be found by the Examiner – permitting a clean prosecution history to explain why an apparent ambiguity is just that or letting the applicant correct the ambiguity.

§ 11[a][4] Focus on the Three Critical Application Elements

The claims, Summary of the Invention and the Detailed Description represent the three most critical elements of any patent application.

Except in the case of a purely defensive patent position, the claims represent the focal point of the drafting exercise throughout as the claims are drafted first and then the remaining pieces of the puzzle are put together to complement the claims.

The Summary of the Invention is the next most important section of the application that should be titled as such and precede the "guts" of the specification, the Detailed Description. The positioning of the Summary of the Invention is explained in the 1949 first edition of the Manual of Patent Examining Procedure: "A brief summary of the invention … should precede the detailed description." MPEP § 608.01(d), *General Statement of Invention* (1949 first edition), quoting Rule 73).

The Summary of the Invention may play a valuable role in providing the type of coverage the applicant needs:

An element in the claims may need a more precise definition. The element (in quotation marks) can be defined after its first usage in the Summary of the Invention.

To cabin the "broadest reasonable interpretation" of a term in the claim during a post grant trial at the Patent Trial and Appeal Board the term can be defined in the Summary of the Invention.

To provide a broad interpretation for an element which is exemplified by only one embodiment in the Detailed Description the recitation of that element in

the Summary of the Invention can be followed by a list of representative examples of suitable embodiments.

The Detailed Description is the final separately titled section (often with an intermediate Brief Description of the Drawings). Whereas concise statements are important for the Summary of the Invention, the Detailed Description should not, for most cases, be necessary for the Examiner's understanding of the invention. Except in biotechnology and other unpredictable areas of technology, everything the Examiner needs for tasks should be found in the claims and the Summary of the Invention. Hence, as many examples as available may be included in the Detailed Description which will help bolster the patentee's position in litigation – or in defense of a post grant proceeding at the Patent Trial and Appeal Board.

§ 11[a][5] A Simple, Easy to Examine Patent Application

A primary goal of the patent drafting process is to create a neat, clean set of patent claims as part of an easy to examine application, one that the Examiner will be predisposed to allow if there is patentable subject matter in the case.

Put oneself in the shoes of the Examiner when he or she first picks up the case for examination: The application should be simple for examination first in terms of the layout of the specification, for example, with headings for the Summary of the Invention which should have self-contained definitions of all claim terms and (particularly for chemical cases) state the utility of the invention; the application have a minimum number of claims, a minimum number of prior art references and a citation of prior art but without an discussion, and an Abstract of the Disclosure closely tracking the language of "claim 1".

§ 11[a][6] Critical First Impression by the Patent Examiner

The patent draftsman must appreciate that the Examiner's first impression of an application which is cleanly and sharply presented will predispose the Examiner toward reaching a favorable conclusion unless the Examiner finds unexpected prior art that was not found by the applicant. Thus, the claims in an ideal situation will be relatively few in number – certainly less than twenty and preferably not more than seven or eight; a Summary of the Invention section will have a verbatim recitation of the claimed invention but with definitions of all otherwise ambiguous terms an a statement of use:

The best prior art will be cited – limited to the closest prior art (or, if there are two or three references that are about equally remote from the claims, then all two or three such references); and no argumentation about the prior art will be present (but if the most relevant passage is buried in a long reference, then that passage is cited by page number). All of the information needed to examine the applications are thus fairly and directly presented in what has become an easy-to-examine application. (The Detailed Description of the invention which discloses multiple embodiments of the invention is segregated by the title "Detailed Description"; all the information needed for examination precedes this often lengthy section which therefore does not need careful study.)

§ 11[a][7] Minimum Number of Claims

One of the biggest mistakes that is routinely made is where the applicant files too many claims. Rather, the goal of patent drafting should be to focus on a minimum number of claims. The application with seven or eight claims is almost always better than the application with seventy or eighty claims.

Must one limit oneself to seven or eight claims?

Of course not.

There is no statutory limit to the number of claims that an applicant presents. He may, for example, choose to present, say, 150 claims. Must one limit oneself to citation of, say, two or three prior art references? Of course not. One may cite, for example, forty or more references.

But, what is the impact on the Examiner who picks up a case for first action with 150 claims and 40 prior art references? Hostility comes to mind. The Examiner perceives an application that was written by an inexperienced practitioner where it is likely that there are numerous formal and other issues present in a case that will be difficult to examine – and one where there is almost no likelihood of a conclusion without a refiling by the RCE or continuation route. Given that there is almost no likelihood of an allowance in the near term, the Examiner is pushed into an adversarial role. The claims will be nitpicked for formalities. Large numbers of prior art references are likely to be cited with multiple rejections.

Clearly, the practitioner who files 150 claims is following a strategy that is not designed to secure prompt allowance of an application. There also is every likelihood that the claims have multiple defects as it is clearly more difficult to

craft an integrated patent document with 150 claims than seven or eight claims. And, the proper drafting of a set of seven or eight claims may very well in the end provide better protection than the application with 150 claims.

§ 11[a][8] Minimum Number of Prior Art Citations

Even more to the point in terms of relations with the Examiner, the applicant who merely dumps forty references into the Patent Office via an Information Disclosure Statement is implicitly saying, "I don't have to find the most pertinent reference. That's your job, Mr. Examiner." Furthermore, there is an implicit thought on the part of some Examiners that where, say, forty references are cited, the applicant is hiding the best of the forty in such a bulk citation of references.

§ 11[a][9] Neutral, Non-Argumentative Specification

The problem of too many claims and too many prior art references is further compounded when the specification (or Information Disclosure Statement) contains an argument of patentability over the prior art. In the first instance, given the prior art, it is the Examiner's task to determine whether there is or is not a prima facie case of obviousness. By providing pre-examination arguments in favor of patentability, this creates an adversarial atmosphere that is bound to trigger a first action rejection.

One of the consequences of overloading an application with too many claims and too many prior art references is that both the patent applicant and the examiner may miss potentially valid issues of indefiniteness under 35 USC § 112(b). The Examiner clearly does not have enough time allotted to go through all the formal issues that may be involved with a 150 claim – 40 reference case: It will be all that

the Examiner can do to examine a case for patentability under 35 USC § 103. Issues will be missed by both the patent attorney and the Examiner.

If there were only a handful of claims and a handful of prior art references, then it is highly probably that issues under 35 USC § 112(b) would be caught by the Examiner: The applicant would then have a chance to either present arguments explaining the clarity of the claims (thus presenting a cleaner prosecution history) or if the rejection is valid, have a chance to amend the ambiguous phrase to obtain a patent clear from problems under 35 USC § 112{b}.

§ 11[b] Specific Reasons Should Exist to Present Each Claim

§ 11[b][1] "Claim Differentiation"

"Claim differentiation" means that where there is an independent and dependent claim and a particular feature is defined in the dependent claim, the independent claim must be given *at least as broad* an interpretation as the dependent claim. It was thus thought that to emphasize the breadth of a particular claim, a dependent claim should be included in the patent that would force a broad construction of the claim of interest.

In recent years, however, "claim differentiation" is not a hard and fast rule. It is no longer necessary to provide a second claim to establish breadth of the first claim through claim differentiation: "The doctrine of claim differentiation creates a presumption that distinct claims, particularly an independent claim and its

dependent claim, have different scopes." *World Class Tech. Corp. v. Ormco Corp*., 769 F.3d 1120, 1125 (Fed. Cir. 2014)(citing *Kraft Foods, Inc. v. Int'l Trading Co*., 203 F.3d 1362, 1368 (Fed. Cir. 2000)).

"[C]laim differentiation is a rule of thumb that does not trump the clear import of the specification[.]" *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1323 (Fed. Cir. 2011)(Lourie, J.)(quoting *Edwards Lifesciences, LLC v. Cook Inc.*, 582 F.3d 1322, 1331 (Fed. Cir. 2009)). Thus, "[w]hile claim differentiation may be helpful in some cases, it is just one of many tools used by courts in the analysis of claim terms." *Edwards Lifesciences*, 582 F.3d at 1331(quoting *Netcraft Corp. v. eBay, Inc*., 549 F. 3d 1394, 1400 n.1 (Fed. Cir. 2008)).

Thus:

"[C]laim differentiation is merely a presumption. It is 'a rule of thumb that does not trump the clear import of the specification.' *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1323 (Fed. Cir. 2011); see also *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1359 (Fed. Cir. 2012) (en banc) ('[C]laim differentiation is not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.') (citation and quotation omitted). Because the ordinary meaning of 'virtual machine' is clear in light of the specification and prosecution history, claim differentiation does not change its meaning."
CardSoft (Assignment for the Benefit of Creditors), LLC v. Verifone, Inc., 769 F.3d 1114, 1119 (Fed. Cir. 2014)(Hughes, J.).

The limited value of "claim differentiation" was more recently emphasized by Circuit Judge Newman:

Although claim differentiation is a useful analytic tool, it cannot enlarge the meaning of a claim beyond that which is supported by the patent documents, or relieve any claim of limitations imposed by the prosecution history. *See, e.g.*, *Retractable Techs.*, 653 F.3d at 1305 ("[A]ny presumption created by the doctrine of claim differentiation 'will be overcome by a contrary construction dictated by the written description or prosecution history.'" (quoting *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005))); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999)("[T]he doctrine of claim differentiation does not serve to broaden claims beyond their meaning in light of the specification, and does not override clear statements of scope in the specification and the prosecution history."(citation omitted)).

Fenner Investments, Ltd. v. Cellco Partnership, __ F.3d __ (Fed. Cir. 2015)(Newman, J.)

§ 11[b][2] Narrow Claims to Pin Patentability on Unexpected Results

A claim to *just* the product to be marketed is much stronger than a generic claim, particularly in the pharmaceutical field. Even if, *arguendo*, the pharmaceutical that is marketed is *prima facie* obvious, that product, *itself*, is often distinguished from amongst even closely related homologs, analogs and isomers by having some superior property. And, above all, the product that goes on the market will have overwhelming commercial success vis a vis the structurally related compounds that often have never gotten past a post-doctoral researcher's laboratory experimentation.

If one has only generic coverage, third parties will seek to attack any showing of unexpected results by admitting, *arguendo*, that the particular pharmaceutical that is marketed is unexpectedly superior to the prior art analogues, but that the claim covers *other* products that are *not* superior to the prior art analogues and surely do not enjoy commercial success of any kind. On this basis, it may be argued that the *generic* invention lacks any unexpected result or commercial success. Such a line of argumentation simply cannot be made against a species claim to the commercial product.

Generic coverage is thus a bonus but distinct from the overriding importance of coverage of what the company itself will invest, often including hundreds of millions of dollars for regulatory approvals. [There is nothing wrong with generic claims as a way of attacking third parties from entering with their own products (or, more likely, providing basis for getting royalties or other consideration).]

§ 11[b]]3] Species Claims

For the "upstream" pioneer invention from universities and startups that opens the door to a new field of research but where there is no *specific* product ready for commercialization, generic protection is the entire patenting exercise. Conversely, for a "downstream" product that will go through the regulatory approval process which is an adjacent homolog of a compound for the same usefulness, here, the patentee is limited to species protection. More importantly, species protection may be all that is needed: The epitome of the value of species protection is found in terms of commercial pharmaceutical patents such as the Enovid® patent or the Plavix® patent which was worth many billions of dollars in terms of profits for a blockbuster drug, Badorc *et al.*, U.S. Patent 4,847,265. The

recently expired patent on Lipitor® generated revenues of $ 13 billion for the last year before expiration of the patent.

§ 11[c] Taming the 800 Pound Gorilla of Patent Drafting

Are claims important for *every* patent? Beyond the statutory requirement to have at least one claim, the answer is, absolutely not!

If the business objective is purely defensive in nature, then the specification is key and claims play a subsidiary role. But, for every case where there is an offensive component, it is the claims that form the centerpiece of the application process. This means that drafting *starts* with the claims and – after completion of the claims, and only then – the rest of the application is put together to complement the claims.

As part of the holistic theme of a simple and easy to examine application, the minimum number of claims should be presented consistent, however, with as many claims as required to meet the business objectives of the applicant. This should normally mean seven or eight or so claims – and not seventy or eighty or so claims. Crafting generic coverage that telescopes through several claims from very broad to narrow should be an objective of many offensive patenting strategies. Filing too many claims not only obfuscates the invention to make examination more complex, but, for example, if there are very many claims this increases the likelihood that one or more of the claims has a coinventor *different* from the named applicant – opening the door to that unnamed coinventor being joined as part of the inventorship and having a *right* to independently license *all* claims of the patent without consent of the original applicants. One of the reasons why there are often too many claims is

because a rational reason to introduce the claims has not been a focal point. Merely because a regular filing fee includes the right to file twenty claims should not be taken as an invitation to file twenty claims.

Combination claims present a special challenge. The temptation is to draft a claim to include all elements of the combination. To do so runs the risk that a competitor can simply *omit* one of the elements to avoid infringement altogether.

While a claim with all elements of the invention is perfectly acceptable for an application, broad protection means that "claim 1" should be drafted with only an element or subcombination of elements, the minimum aspects of the disclosed invention that passes patentability muster.

§11[c][1] Claims with Varying Numbers of Elements

To simply draft a claim with every element from the drawings is likely to provide a patent that may be next to worthless. The "all elements" rule is one of the most important aspects of the patent law for the draftsman and must be thoroughly understood as will be seen from a discussion of the *Pennwalt* case later in this book.

Under the "all elements" rule of the *Pennwalt* case, if there is a claim to a combination of elements (a), (b), (c) and (d), and element (c) is *unnecessary* to achieve the result of the combination or otherwise trivial or unimportant, infringement still depends upon finding that the accused infringer uses *all* of the elements. Therefore, good claim drafting requires that element (c) not be included in the generic claim.

For generic "claim 1", any element that is both unnecessary to the success of the combination and also unnecessary for establishing patentability should be *deleted* from any proposed claim 1.

The ideal "claim 1" will have *only* one or two elements which are necessary to establish patentability over the prior art. This will be the broadest claim in the case.

§11[c][2] Generalized Descriptions of Each Element

It is important to understand whether a particular element *as described in the drawings* is necessary to establish patentability over the prior art. For example, if one of the elements is a screw, then a claim which recites that element as a screw may be insufficient to provide coverage against a competitor's embodiment that utilizes a nail or even glue to hold two parts together. Therefore, instead of a "screw" a "fastener" might be described in claim 1.

§11[c][3] Claims Removed from the Closest Prior Art

An original application is often filed with a clear idea of the generic scope of protection but without a concrete idea as to the identity of the ultimate commercial species. The development process for bringing an invention to market must consider a variety of factors that can sometimes lead to a late choice as to the commercial embodiment, often long after the filing date.

Particularly if the commercial embodiment is more removed from the prior art than the closest embodiment in the generic claims, it is important to have a claim focused on the commercial embodiment that will present a stronger case for validity than the generic claim.

From the standpoint of nonobvious properties of the commercial embodiment it is important to reconsider claiming strategy late in prosecution to take into account the commercial choice for the preferred embodiment and to have claims either keyed to that commercial embodiment *or* to a subgeneric definition of the invention having a nexus to properties to establish nonobviousness. *See* §3[a][4], *Claim Keyed to a Nonobvious Feature.*

(Manifestly, if the commercial embodiment is not disclosed in the original application, then a new application should be filed to that embodiment where nonobvious features or secondary considerations of nonobviousness may nevertheless be basis for patentability.)

The importance of having claims of limited scope remote from the prior art is explained by the late Chief Judge Markey in *In re Payne*, 606 F.2d 303 (CCPA 1979) where broad claims were denied because although unexpected results were shown that normally would establish nonobviousness, here, the claims were drafted too broadly to permit a conclusion that the range of compounds embraced by the claims would have unobvious properties:

"A prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381, 386-87 (CCPA 1963). Direct or indirect comparative testing between the claimed compounds and the closest prior art may be necessary. *In re Merchant*, 575 F.2d 865, 869 (CCPA 1978); *In re Blondel*, 499 F.2d 1311, 1317, (CCPA 1974); In re *Swentzel*, 219 F.2d 216, 220 (1955). Contrary to the board's apparent suggestion, an applicant need not test compounds taught in each and every reference. *In re Holladay*, 584 F.2d 384, 386 (CCPA 1978). However, where an applicant tests less than all the cited compounds, the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant's claimed compounds and the compounds of the closest prior art. *In re Holladay*, supra at 386, *In re Merchant*, supra at 869. Payne's tests are insufficient to permit that conclusion."
Payne, 606 F.2d at 315-16 (emphasis added)

§11[c][4] **Claim Nexus Keyed to a Nonobvious Feature**

If the commercial embodiment of the invention has special characteristics or other basis to establish nonobviousness, it is important that a claim be presented that is keyed to the nonobvious feature in order to be able to rely upon the nonobvious feature to sustain patentability or validity.

The issue of nexus was explained by Judge Linn in *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011), in the context of secondary considerations of nonobviousness. Secondary considerations of nonobviousness must always be considered:

> "[W]hen secondary considerations are present, though they are not always dispositive, it is error not to consider them. *See Stratoflex v. Aeroquip Corp*., 713 F.2d 1530, 1538 (Fed. Cir. 1983) ('[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness.'); *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348, 1372 (Fed. Cir. 2007) ('Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion.')." *Kao*, 639 F.3d at 1067-68.

But, even where there is evidence of secondary considerations supporting a conclusion of nonobviousness, the evidence must support the full scope of the claimed invention and there must be nexus between the evidence and the merits of the *claimed invention*. As explained in ***Kao:***

Evidence of secondary considerations must be reasonably commensurate with the scope of the claims. See *In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971); *In re Hiniker*, 150 F.3d 1362, 1369 (Fed. Cir. 1998). This does not mean that an applicant is required to test every embodiment within the scope of his or her claims. If an applicant demonstrates that an embodiment has an unexpected result and provides an adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner, this will generally establish that the evidence is commensurate with scope of the claims. *See In re Greenfield*, 571 F.2d 1185, 1189 (CCPA 1978) (concluding that evidence of secondary considerations was not commensurate with the scope of the claims where that evidence related to a single compound and there was no adequate basis to conclude that other compounds included within the scope of the claims would exhibit the same behavior); *In re Cescon*, 474 F.2d 1331, 1334 (CCPA 1973) (concluding that, although not every compound within the scope of the claims was tested, the evidence of secondary considerations was sufficient where evidence showed a correlation and there was no factual basis to expect the compounds to behave differently in different environments).

But there is a more fundamental requirement that must be met before secondary considerations can carry the day. "For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*." *Wyers v. Master Lock Co*., 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quotation omitted). Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention. *Tokai Corp. v. Easton Enters., Inc*., 632 F.3d 1358, 1369 (Fed. Cir. 2011) ("If commercial success is due to an element in the prior art, no nexus exists."); *Ormco Corp*., 463 F.3d at 1312 ("[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent."); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) ("The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims .... [and] in such a situation, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range." (citations omitted)).

Kao, 639 F.3d at 1068.

In the *Tiffin* "cup case" cited in *Kao* the applicant invented thin-walled cups for commercial coffee dispensers which were commercially successful versus the thicker-walled, previously used foam cups. ***In re Tiffin,*** 448 F.2d 791 (CCPA 1971)(per curiam)(on reh'g). In the original decision of the Court the evidence of commercial success was basis for grant of claims to *any* container made from this thin-walled material as well as claims limited to "cups". On petition for reconsideration by the Patent Office, the Court agreed that only claims keyed to the commercial success were patentable based upon the limited scope of evidence of nonobviousness:

> The Patent Office petitions for a … modification of our decision… The solicitor[ ]… concedes to appellant claims [ ] drawn to processes of making "cups," … but asks reversal of our decision as to claims [ ] drawn broadly to processes of making "containers," and claims [ ] drawn to "containers."
>
> This distinction between the two groups of claims is based … the ratio decidendi of our opinion, which was that appellants' evidence of commercial success and the satisfaction of a long-felt need, both the success and the need being with respect to "cups" used in vending machines, was sufficient to overcome the Patent Office's case of prima facie obviousness. The solicitor's position is that the objective evidence of non-obviousness is not commensurate with the scope of claims [ ] reciting "containers" generally, but establishes non-obviousness only with respect to "cups" and processes of making them. We agree.
>
> ***
>
> [I]t it is the view of this court that objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. *In re Law*, 303 F.2d 951, 954 (CCPA 1962); *In re Kennedy*, 436 F.2d 1394, 1399 (CCPA 1971); and *In re McLaughlin*, 443 F.2d 1392, 1396-97 (CCPA 1971). Here, appellants' claims [to containers] are too broad in the sense of 35 USC 103 in that they are inclusive of subject matter which is prima facie obvious and concerning which appellants have not rebutted the Patent Office's prima facie case.

Tiffin, 448 F.2d at 791-92.

The *Manual of Patent Examining Procedure* provides guidance in a section excerpted from MPEP § 716.03(a), *Commercial Success Commensurate in Scope With Claimed Invention* [R-2]:

I. EVIDENCE OF COMMERCIAL SUCCESS MUST BE COMMENSURATE IN SCOPE WITH THE CLAIMS

Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791 (CCPA 1971) (evidence showing commercial success of thermoplastic foam "cups" used in vending machines was not commensurate in scope with claims directed to thermoplastic foam "containers" broadly). In order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features. *Joy Technologies Inc. v. Manbeck*, 751 F. Supp. 225, 229 (D.D.C. 1990) , *aff'd*, 959 F.2d 226, 228 (Fed. Cir. 1992) (Features responsible for commercial success were recited only in allowed dependent claims, and therefore the evidence of commercial success was not commensurate in scope with the broad claims at issue.).

An affidavit or declaration attributing commercial success to a product or process "constructed according to the disclosure and claims of [the] patent application" or other equivalent language does not establish a nexus between the claimed invention and the commercial success because there is no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever commercial success may have occurred is attributable to the product or process defined by the claims. *Ex parte Standish*, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988) .

II. REQUIREMENTS WHEN CLAIMED INVENTION IS NOT COEXTENSIVE WITH COMMERCIAL PRODUCT OR PROCESS

If a particular range is claimed, applicant does not need to show commercial success at every point in the range. "Where, as here, the claims are directed to a combination of ranges and procedures not shown by the prior art, and where substantial commercial success is achieved at an apparently typical point within those ranges, and the affidavits definitely indicate that operation throughout the claimed ranges approximates that at the particular points involved in the

commercial operation, we think the evidence as to commercial success is persuasive." *In re Hollingsworth*, 253 F.2d 238, 240 (CCPA 1958) . See also *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387(Fed. Cir. 1988) (where the commercially successful product or process is not coextensive with the claimed invention, applicant must show a legally sufficient relationship between the claimed feature and the commercial product or process).

The *Manual of Patent Examining Procedure* provides further guidance in MPEP § 2163, *Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement* [R-5]:

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) ; *Enzo Biochem*, 323 F.3d at 968 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., In re Wright, 866 F.2d 422 (Fed. Cir. 1989)) , whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290 (Fed. Cir. 2002) ; *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) ; Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993) *; In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993)) , or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., Fields v. Conover, 443 F.2d 1386 (CCPA 1971)) . Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563 (Fed. Cir. 1991).

As seen from *In re Hiniker*, 150 F.3d 1362 (Fed. Cir. 1998)(Clevenger, J.), it is manifest that a showing of nonobviousness must be keyed to a *claimed* feature of the invention, as opposed to a feature that is disclosed but not claimed in the application: “

Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982). When given their broadest reasonable interpretation, the claims on appeal sweep in the prior art, and the prior art would have directed an artisan of ordinary skill to make the combination cited by the examiner. *** [Reexamination patentee] Hiniker's *** evidence of secondary considerations of nonobviousness, are not commensurate with the claim scope and are therefore unpersuasive. The invention disclosed in Hiniker's written description may be outstanding in its field, but the name of the game is the claim. *See* Giles Sutherland Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 Int'l Rev. Indus. Prop. & Copyright L. 497, 499 (1990) ('The U.S. is strictly an examination country and the main purpose of the examination, to which every application is subjected, is to try to make sure that what each claim defines is patentable.

To coin a phrase, *the name of the game is the claim*.')."
Hiniker, 150 F.3d at 1368-69 (original emphasis).

Tiffin and *Hiniker* are followed in *Allergan, Inc. v. Apotex Inc*., 754 F.3d 952 (Fed. Cir. 2014)(Prost, C.J.). As explained by the Chief Judge:

"The district court's findings on secondary considerations [as establishing patentability] suffer from the [ ] infirmity of lacking a nexus with the scope of the [ ] claimed invention. It is the established rule that 'objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.' [*In re*] *Tiffin*, 448 F.2d 791, 792, (CCPA 1971); *see also MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc*., 731 F.3d 1258, 1264-65 (Fed. Cir. 2013); *In re [ ] Kao*, 639 F.3d at 1068; *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); *In re Hiniker Co*., 150 F.3d 1362, 1369 (Fed. Cir. 1998). …[T]he district court's findings on unexpected results, which were closely inter-twined with its analysis of motivation to combine and reasonable expectation of success, were not commensurate with the full scope of the patent's claims."

Allergan v. Apotex, 754 F.3d at 965.

"Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ortho-McNeil Pharm, Inc. v. Teva Pharms. Indus*., 344 Fed. Appx. 595, 600 (Fed. Cir. 2009)(quoting Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311-12 (Fed. Cir. 2006)).

As seen from the statement of Circuit Judge Newman, it is imperative that a showing of nonobviousness be against the closest prior art:

The provision of comparative data … is long-established practice. See In re Payne, 606 F.2d at 315-16 ("A prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. Direct or indirect comparative testing between the claimed compounds and the closest prior art may be necessary." (citing *In re Papesch*, 315 F.2d 381, 386-87 (CCPA 1963))); *In re Merchant*, 575 F.2d 865, 869 (CCPA 1978) ("An applicant relying upon a comparative showing to rebut a prima facie case must compare his claimed invention with the closest prior art."); *In re Miller*, 197 F.2d 340, 342 (CCPA 1952) ("Where, as here, results superior to those produced by the references of the prior art, or public knowledge and use, constitute the basis for the claim of invention, the making of comparative tests and the establishment of the unexpected and superior results never before attained must be established by a proper showing.").

Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc., 769 F.3d 1339, 1348-49 (Fed. Cir. 2014)(Order)(Newman, J., joined by Lourie, Reyna, JJ., dissenting from den. reh'g en banc)(emphasis supplied)

The *Manual* explains the nexus requirement in § MPEP § 716.01(b), Nexus Requirement and Evidence of Nonobviousness:

TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS **REQUIRED)**

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39 (1966) .

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42 (Fed. Cir. 1985)[ ]. The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd*., 851 F.2d 1387 (Fed. Cir. 1988).

§ 11[d] *Steenbock* "Rings" of Plural Generic Definitions

"Layered" generic disclosure in a first application is an important prophylactic against the possibility that the ultimate generic protection needed in a later filing will find basis in the first filing. For example, consider the situation where working examples show that particular alloys with 3.0 % nickel and 4.7 % nickel are highly suitable and the generic disclosure coves from 2.0 to 5.0 % nickel, what happens if it is later discovered that 7.5 % nickel is suitable? Under *The Steenbock* line of case law a continuing application with a claim of up to 8.0 % nickel could be denied. *See In re Steenbock***,** 83 F.2d 912 (CCPA 1936); *In re*

Ruscetta, 255 F.2d 687 (CCPA 1958)(Rich, J.). Instead, the original application should have "layers" of generic protection. For example, the generic disclosure could be of, say, 2.0 to 10.0 % nickel, with subgeneric layers defining amounts of up to 9.0 %, and up to 8.0 % and so forth. Such "layers" can thus provide specific basis for priority.

If the patentee has drafted his original specification without a correct generic statement of the invention, the failure to provide such a generic statement may mean that any continuation-in-part application adding such a generic statement may stand naked as of the continuation-in-part filing date. Hence, intervening prior art that would be a statutory bar where there is no benefit of the earlier filing date will constitute a statutory bar under the *Steenbock* line of case law.

§ 11[d][1] **Claim by Claim Priority Basis**

Priority based upon an earlier application depends upon whether a *particular claim* is entitled to priority, as opposed to whether "the application" is entitled to such priority. (Often, because an identical issue as to priority is dispositive for all claims, the issue is phrased with less precision as to whether "the application" is entitled to priority.)

Thus, "*a claim* in a later application receives the benefit of the filing date of an earlier application so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, including the written description requirement, *with respect to that claim*." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir., 2008)(Plager, J.)(citing *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed.Cir.1994)(emphasis added).

Drafting a generic definition for an invention at the time of the first filing is a most difficult but important challenge. If, say, a new invention involves a composition where there are examples that the composition includes 3.0 % Scrontium, 4.3 % Scrontium, 7.0 % Scrontium, 8.5 % Scrontium, one might consider the following generic definitions, and where the best results are from 4.0% Scrontium up to 8.0 % Scrontium. Several generic definitions may be contemplated:

[a] … wherein the composition includes at least 2.0 % Scrontium.
[b]… wherein the composition includes at least about 3.0 % Scrontium.
[c]… wherein the composition includes from about 2.5 % to about 9.0 % Scrontium.
[d] wherein the composition includes at least 2.0 % up to 9.0 % Scrontium.
[e] wherein the composition includes at least 4.0 % to 8.0 %Scrontium.

For the initial application, it is not wrong to have several *alternate* definitions in the original specification. If, a year after filing a provisional with the above definitions, it is discovered that all commercial embodiments and likely commercial embodiments have at least 4.0 % Scrontium and up to 7.0 % Scrontium, the following claims could be presented in the regular application:

1. A composition which includes at least 4.0 % to 8.0 % Scrontium.

2. A composition of claim 1 which includes up to 7.0 % Scrontium.

Claim 2 represents the preferred generic range, while claim 1 presents a range fully supported in the parent application (example [d]). It is important that claim 1 be maintained in the application and resultant patent in case intervening prior art is uncovered. Then, even if it is not possible to sustain priority for the preferred claim 2 range, *at least* claim 1 remains untouched by the intervening prior art.

Thus, it is important whenever a change is made in the definition of the subject matter in the claims to *maintain* at least one or more claims with the original definition in the first filing. Thus, if the claims with the changed definition are held to be restricted to their actual filing date and there is intervening prior art between the parent and later applications, at least the *maintained* claims will be entitled to priority as of the parent date and thus overcome the otherwise intervening prior art.

A good example of the challenges for priority with changes in ranges is found in *In re Wertheim*, 541 F.2d 257 (CCPA 1976), where there were several sets of claims some of which were entitled to priority while others were not – and thus defeated by intervening disclosure. *See* MPEP § 2163.05(III) , *Changes to the Scope of Claims* [R-11](2013)("In the decision in *In re Wertheim* [ ] the ranges described in the original specification included a range of '25%- 60%' and specific examples of '36%' and '50%.' A corresponding new claim limitation to 'at least 35%' did not meet the description requirement because the phrase 'at least' had no upper limit and caused the claim to read literally on embodiments outside the '25% to 60%' range, however a limitation to 'between 35% and 60%' did meet the description requirement.")

§ 11[d][2] **Priority to Genus of Different Scope**

It has long been well established that a generic claim may not be entitled to priority based upon an earlier application where the genus in the later application does not find "written description" support in the earlier application. This is particularly important in the case of a strategy of sequential filings where the earliest application has sparse (if any) generic disclosure and then a later application *does* have a generic claim and disclosure:

Under cases that include *Steenbock* and *Ruscetta*, there is a two-fold inquiry: *First*, for a claim to a generic invention in a daughter application, does the parent application provide a "written description" basis for that genus? Phrased differently, if an amendment had been made to add the later generic invention, would that amended generic definition find basis for support in the original parent application?

If the answer to the question of support is "no", there is no written description of the generic claim in the parent, then the daughter application that claims priority to the earlier application would *not* be entitled to priority based upon the parent application, and hence would stand naked as of the later filing date.

Given that the *Leahy Smith America Invents Act* broadens the scope of prior art, there is a greater likelihood that there will be intervening prior art either by the applicant or a third party. To be sure, a large percentage of the case law prior to the *Leahy Smith America Invents Act* involved factual situations such as in *Steenbock* and *Ruscetta*. In the *Ruscetta* case the original parent Ruscetta application disclosure was published in the form of the counterpart British specification. The parent application (and hence the British counterpart published specification)

In simplified form, the first Ruscetta and Jenny filing claimed a method of etching a metal species – tantalum – while the application at the Court claimed a method of etching the same species – tantalum – or a related metal (zirconium, niobium or titanium). Intervening prior art was the Ruscetta and Jenny publication essentially *identical* to the parent: It was the British counterpart published application to the method with tantalum. There clearly was *priority* for

the tantalum species. But, priority was not the issue in *Ruscetta:* Rather, the issue was whether Ruscetta and Jenny were entitled to rely on the parent filing date under what is today 35 USC § 112(a). They clearly were not.

Therefore, the *Ruscetta and Jenny* claims at the court stood naked as of their later filing date; hence, their claims were barred by their own disclosure of the tantalum species in the British counterpart application. *Ruscetta* broke no new legal ground but essentially reprised the *Steenbock* case. As explained by Judge Rich in *Ruscetta:*

[T]he the present case is an exact parallel to the situation in the *Steenbock* case. The application [in *Steenbock*] disclosed and claimed the irradiation of fungus material broadly. It was filed [in 1932] as a continuation-in-part of an application filed [in] 1926, which did not disclose the broad genus "fungus material," but only a specific fungus, yeast. The references [included] Steenbock's own British specification published [in] 1926. Steenbock was allowed his specific yeast claims, supported by his parent application, because there was no [ ] statutory bar against them …. But as to the broad fungus material claims, [the intervening British specification and other prior art] were held to be statutory bars … by the Board of Appeals. … The board's finding was that because of the lack of supporting disclosure for broad fungus claims in the parent applications, Steenbock had to rely on his 1932 filing date and therefore the references were … statutory bars as to it; and this court, after restating the board's rejection as having been 'for the reason that each of the references * * * was published more than two years prior to the filing of the involved application,' affirmed that rejection. The Steenbock case is therefore directly in point and clear authority for the rejection of the broad claims herein."

Ruscetta, 255 F.2d at 690.

Steenbock in turn cites to case law that is now more than 100 years old for the proposition that "[t]he principle is well established … that the disclosure of a species in a cited reference is sufficient to prevent a later applicant from obtaining generic claims, although the disclosure in an application of a species may not be a sufficient basis for a generic claim." *In re Steenbock***,** 83 F.2d 912 (1936)(citing *In*

re Ellis, 37 App. D.C. 203 (1911); *In re Dosselman*, 37 App. D.C. 211 (1911); *In re Langmuir*, 62 F.2d 93 (CCPA 1932); *In re Walker*, 70 F.2d 1008 (CCPA 1934), *In re Burk*, 74 F.2d 547 (CCPA 1935)).

In *In re Herschler*, 591 F.2d 693 (CCPA 1979), a parent application (the "great-grandfather" case) disclosed various species (gluco-corticosteroids) whereas the instant claims on appeal are much broader, some directed to steroids, generally, or to a group of steroids broader than the gluco-corticosteroids of the great-grandfather case. Intervening prior art was held to bar the broader claims because the narrow disclosure in the earlier case did not provide basis for the generic claim in the later case: "[T]he great-grandparent case *** disclosure is limited to gluco-corticosteroids whereas all of the present claims on appeal are drawn either to steroids in general or to steroids not limited to glucocorticosteroids[ ]. It is now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim." *Herschler*, 591 F.2d at 696 (citing *In re Ruscetta*, 255 F.2d 687 (CCPA 1958); *In re Lukach*, 442 F.2d 967 (CCPA 1971); *In re Smith*, 458 F.2d 1389 (CCPA 1972)).

Therefore, "appellant may not rely upon his great-grandparent case to support any of the claims on appeal and thus the [intervening] prior art … can be properly applied against the claims under 35 USC 102(b) and 103." *Herschler*, 591 F.2d at 697.

Whether a new generic or subgeneric definition of an invention is entitled to priority is a very case-specific determination, as shown in a footnote citing a variety of cases in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1568-69 n.6 (Fed. Cir. 1991)(Rich, J.)("*Chester v. Miller*, 906 F.2d 1574 (Fed.Cir.1990) (parent

application's disclosure of chemical species constituted 102(b) prior art against continuation-in-part (c-i-p) application on appeal, but did not provide sufficient written description to support c-i-p's claims to encompassing genus); *In re Gosteli*, 872 F.2d 1008 (Fed.Cir.1989) (foreign priority application's disclosure of chemical subgenus was insufficient written description to support genus claims of corresponding U.S. application); *In re Wright*, 866 F.2d 422 (Fed.Cir.1989) (application in 'clear compliance' with Sec. 112 'written description' requirement with respect to claim limitation that microcapsules were 'not permanently fixed'); *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed.Cir.1988) (holding generic interference count to scroll compressor supported by written description of foreign priority application, the court stated, 'A specification may, within the meaning of 35 U.S.C. Sec. 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses'); *Kennecott Corp. v. Kyocera Int'l, Inc*., 835 F.2d 1419 (Fed.Cir.1987) (parent application's lack of express disclosure of inherent 'equiaxed microstructure' property did not deprive c-i-p's claims to a sintered ceramic body having said property of the benefit of parent's filing date); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570 (Fed. Cir. 1985) (parent application's disclosure provided adequate written description support for certain claim limitations respecting protein content, temperature, and moisture content, but not others);

In re Wilder, 736 F.2d 1516 (Fed. Cir. 1984) (broadly worded title, general description of drawing, and objects of invention of parent patent application did not adequately support reissue application claims directed to genus of indicating mechanisms for dictating machines); *In re Kaslow*, 707 F.2d 1366 (Fed.Cir.1983) (claims to method of redeeming merchandise coupons, comprising step of

providing an audit of coupon traffic, were not supported by specification of parent application).")

§ 11[d][3] *Steenbock* Applies to Provisional Priority

The law of *Steenbock* applies equally to a provisional application: For priority purposes, "the provisional application must describe the invention in such a way that one of ordinary skill in the art 'would understand that the genus that is being claimed has been invented, not just the species of a genus.'" *Trading Techs. Int'l. Inc. v. Espeed Inc*., 595 F.3d 1340, 1350 (Fed. Cir. 2010)(Rader, J.) (quoting *Carnegie Mellon Univ. v. Hoffman-La Roche, Inc*., 541 F.3d 1115, 1124 (Fed. Cir. 2008)).

The theory counter to *Steenbock* is that because a species is disclosed in a parent application that the applicant thus has "possession" of the invention. This argument is answered in *New Railhead:*

"[T]the written description requirement 'is not subsumed by the 'possession' inquiry.' *Enzo Biochem, Inc. v. Gen-Probe Inc*., 42 Fed. Appx. 439, *granting reh'g* at 19 (2002). Identity of description is not necessary. *See, e.g.*, *Crown Operations Int'l, Ltd. v. Solutia Inc*., 289 F.3d 1367, 1376 (Fed. Cir. 2002) ('The disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.'). Identity of that which is described, however, is necessary: 'What is claimed by the patent application must be the same as what is disclosed in the specification . . . .' *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); *accord Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)."

New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1296 (Fed. Cir. 2002)(Michel, J.). *See also Endo Pharms., Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1382 (Fed. Cir. 2014)(Dyk, J., dissenting in part) ('"What is claimed by the patent application [claiming priority to a provisional application] must be the same as what is disclosed in the [provisional] specification.'' *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co*., 298 F.3d 1290, 1296 (Fed. Cir. 2002) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722 (2002)) (citing *Lockwood v. Am. Airlines, Inc*., 107 F.3d 1565, 1572 (Fed. Cir. 1997)); *see also Ariad*

Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1342 (Fed. Cir. 2010). That is to say, a patent claiming priority to a provisional application must cover the same inventive subject matter as the provisional application."); *Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1372 (Fed. Cir. 2013)(Reyna, J., concurring in part and dissenting in part)("[A] non-provisional utility patent application may be afforded the priority date of a related provisional application if the two applications share at least one common inventor and the written description of the provisional application *adequately supports the claims of the non-provisional application*.

To backdate the later application with the earlier priority date, the specification of the provisional application must 'contain a written description of the invention' as defined in § 112 ¶ 1.

New Railhead Mfg., L.L.C., 298 F.3d at 1295 (discussing 35 U.S.C. 119(e)(1) and 35 U.S.C. § 112 ¶ 1).")

§ 11[d][4] **Statutory Bar Intervening Prior Art**

If the claims of a continuing application under 35 USC § 120 are not entitled to priority under *Steenbock* and *Ruscetta* but instead stand naked as of the continuing application filing date, then a prior art event more than one year before the continuing application filing date is a statutory bar to deny patentability to the applicant.

§ 11[d][4][A] **Narrowed Range Barred by Intervening Disclosure**

It is easy to understand the rule that a broadened generic definition is not entitled to priority based upon a narrower disclosure, and that the publication of a foreign counterpart more than a year prior to the filing of the broadened continuation-in-part application is barred under *In re Ruscetta*, 255 F.2d 687 (CCPA 1958)).

It is more difficult to grasp that if there is a broader "generic" invention in a parent application supported by a species in the original parent filing, that *then* a narrower "subgeneric" invention in a continuing application also readable on that species may be barred keyed to the intervening publication of the species in the foreign counterpart of the original parent filing. This is the message explained in *In re Lukach*, 442 F.2d 967, 968-70 (CCPA 1971)(Lane, J.).

In *Lukach* the applicant's original grandparent (and parent) disclosure was directed to a solid elastomeric copolymer of ethylene and propylene where the claims were not limited as to a numerical Mw/Mn ratio while the specification disclosed a specific working example with the ratio

Mw/Mn = 2.6

(Mw is the weight-average molecular weight, and Mn is the number-average molecular weight.) More than one year after the British counterpart of the grandparent was published, Lukach filed a continuing application which now claimed "[a] solid elastomeric copolymer of ethylene and propylene having *** a Mw/Mn ratio of at least 2.0 and less than about 3.0 ***."

Here, although the later claim was *narrowed* and supported by an example the *range* was not supported; therefore, priority was denied and the claim was held anticipated by the intervening publication corresponding to the grandparent application:

> One requirement for obtaining th[e] benefit [of priority based upon a parent application] is that the invention now claimed has to have been disclosed in both the parent and grandparent applications "in the manner provided by the first paragraph of section 112." 35 U.S.C. § 120. Whether it was so disclosed is the issue before us….
>
> * * *

The examiner… was of the view that the "ratio of at least 2.0 and less than 3.0 is not supported in any of the [grandparent application]." The board agreed, stating: "The Examiner's position is that the range recited in the claims is not disclosed in the earlier applications, and we do not find any disclosure of such a range." For this reason… the board held that appellants were not entitled to the benefit of the grandparent application and hence affirmed the § 102 (b) rejection.

[T]he question is whether the parent and grandparent applications disclose, "in the manner provided by the first paragraph of section 112," the invention now claimed. From the board's language it is apparently the description requirement, rather than the enablement provisions or best mode provision, of the first paragraph of § 112, which was considered not to have been met.

[W]here an applicant claims, as here, a class of compositions, he must describe that class in order to meet the description requirement of the statute. See *In re Ahlbrecht*, 435 F.2d 908 (CCPA 1971); *In re DiLeone and Lucas*, 436 F.2d 1404 (CCPA 1971); *In re DiLeone*, 436 F.2d 1033 (CCPA 1971). The question then is whether appellants have done so in the parent and grandparent applications. We agree with the examiner and the board that they have not.

Looking to the grandparent application, we find no express mention of the Mw/Mn ratio of the copolymers described therein. Appellants correctly argue, however, that the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of § 112. See, e. g., *Henry J. Kaiser Co. v. McLouth Steel Corp.*, 257 F.Supp. 372, 429 (E.D. Mich.1966), *affd., Kaiser Industries Corp. v. McLouth Steel Corp.*, 6th Cir., 400 F.2d 36 (6th Cir. 1968)[.]

The matter of what language constitutes sufficient description to support a claim of given breadth has been a troublesome question. See, e. g., the *DiLeone* cases and *In re Ahlbrecht, supra*. An especially difficult aspect of this problem has been the situations involving specifications which describe broader subject matter than is subsequently claimed, e. g., a genus when a subgenus is claimed. Appellants urge that in the instant case their grandparent application disclosed a genus of copolymers having, among other characteristics, "narrow molecular weight distribution," and that they are now further limiting the claims to the subgenus wherein the distribution is indicated by a Mw/Mn ratio between 2.0 and 3.0. They point out that the examiner has agreed that one of the working examples in the grandparent inherently describes a co-polymer which would have a Mw/Mn ratio of 2.6. They then urge that this court's decision in *In re Risse*, 378 F.2d 948, 54 CCPA 1495 (1967), stands for the proposition that an applicant is entitled, as to a claimed subgenus, to the benefit of the filing date of a parent application if the

parent discloses a genus wholly encompassing the claimed subgenus and also discloses a species within that subgenus.

***

We are …left with the single example inherently disclosing a copolymer having a Mw/Mn ration of 2.6. This single example does not alone provide support for the recited range from 2.0 to 3.0, and nothing has been brought to our attention to show that any other language in the grandparent application, taken together with the knowledge of persons skilled in the art, points to the recited range. Accordingly, the grandparent application does not, either expressly or inherently, disclose the invention now claimed, and appellant is not entitled to the benefit of the grandparent filing date. It follows that appellants cannot overcome the § 102(b) time bar arising from publication of the complete specification of their British patent.

Appellants have raised a further point. They contend that "there is an inconsistency constituting an inequity in rejecting the claims as fully met by the Hercules British patent under 35 USC 102, while at the same time holding that appellants cannot obtain the benefit of the filing date of the U. S. counterpart." What they are saying, in terms of the statute, is that if "the invention was * * * described" in the British reference within the meaning of § 102(b), there must have been a "description of the invention" in the corresponding grandparent application within the meaning of the first paragraph of § 112. This argument appears to overlook the law that the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes (see, e. g., *In re Ruscetta*, 255 F.2d 687 (CCPA 1958)), whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. See, e. g., *In re Ahlbrecht, supra*. There are other apparent anomalies between the requirements for claim-anticipating disclosures and for claim-supporting disclosures. See, e. g., *In re Hafner*, 410 F.2d 1403 (CCPA 1969). If the law in these situations really produces inequities, the proper remedy is in Congress.

§ 11[d][5] **Unclaimed Disclosure to Provide Basis for Later Claims**

As explained in § 613, *Disclosure is Key to International Patent Regime Priority*, priority is based upon supporting *disclosure* in the parent application which may or may not include a *claim* in the parent application.

Where a preferred range or subgenus is appreciated at the time of the original filing that preferred range or subgenus should be *disclosed* even if it is not claimed in the original application. Disclosure of the range or subgenus opens the door to filing a continuation-in-part or continuation application that now specifically claims the preferred range or subgenus.

With a specific *disclosure* in the original application of the range or subgenus, the possibility exists that priority would be denied in a continuing application. Thus, filing a continuing application – whether labeled a "continuation" or "continuation-in-part" is dangerous where a claimed generic parameter is changed because if the continuing application is filed more than thirty months from the earliest priority date, there is a danger that the claim in the continuing application will be barred as anticipated by the original 18 month publication of the original application. A good example is *In re Lukach*, 442 F.2d 967, 970 (CCPA 1971)(Lane, J.), which is the subject of § 154, *Narrowed Range Barred by Intervening Disclosure.*

In *Lukach* there was no publication of the original United States application but instead the British counterpart of that application was published more than one year before the filing date of the latest Lukach application which, for the first time, claimed a ratio of two components within a range of 2.0 to 3.0, supported in the original and all relevant applications by a working example of the ratio 2.6. The

species with the 2.6 ratio was prior art against the Lukach claim because the *Lukach* claim was not supported in the parent.

The argument was raised that how can an intermediate publication constitute an anticipation of the later claim when priority was denied based upon the identical disclosure: "[Lukach] contend that 'there is an inconsistency constituting an inequity in rejecting the claims as fully met by the [foreign counterpart] patent under 35 USC 102, while at the same time holding that appellants cannot obtain the benefit of the filing date of the U. S. counterpart.'" *Lukach*, 442 F.2d at 970. The Court responded:

> [Lukach argues] that if "the invention was * * * described" in the British reference within the meaning of § 102(b), there must have been a "description of the invention" in the corresponding grandparent application within the meaning of the first par\agraph of § 112. This *** overlook[s] the law that the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes (see, e. g., *In re Ruscetta*, 255 F.2d 687 (CCPA 1958)), whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. See, e. g., *In re Ahlbrecht, supra*. ***
>
> Appellants … contend that "there is an inconsistency constituting an inequity in rejecting the claims as fully met by the Hercules British patent under 35 USC 102, while at the same time holding that appellants cannot obtain the benefit of the filing date of the U. S. counterpart." What they are saying, in terms of the statute, is that if "the invention was * * * described" in the British reference within the meaning of § 102(b), there must have been a "description of the invention" in the corresponding grandparent application within the meaning of the first paragraph of § 112.

This argument appears to overlook the law that the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes (see, e. g., *In re Ruscetta*, 255 F.2d 687 (CCPA 1958)), whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. See, e. g., *In re Ahlbrecht, supra*. There are other apparent anomalies between the requirements for claim-anticipating disclosures and for claim-supporting disclosures. See, e. g., *In re Hafner*, 410 F.2d 1403 (CCPA 1969). If the law in these situations really produces inequities, the proper remedy is in Congress.

Lukach, 442 F.2d at 970.

§ 11[e] *Steenbock* is Still not Universally Understood

At first blush, it is difficult to understand the *Steenbock* rationale where subject matter in a parent application *identical* to disclosure in a daughter patent application is used as prior art against claims in the daughter application where that "prior art" disclosure is intermediate between the parent and daughter filing dates. How is it possible that disclosure insufficient to support claims in the daughter *is* sufficient to anticipate such claims when that very disclosure is identical to the parent application disclosure? The answer is that *Steenbock* requires a claim by claim analysis: The first issue is whether the claim in the daughter is supported under § 112(a) by the disclosure in the parent? Where the daughter claim is different in scope from the parent disclosure, § 112(a) is not met, so that the daughter claim then stands naked in the daughter filing date. The second issue is whether the disclosure in the parent is "prior art" against the claims of the daughter: Yes, it is, because the daughter claim stands naked as of the daughter filing date. The third issue is a question of anticipation: Does the claim in the daughter application read on an embodiment of the intervening prior art publication? Yes, it does: the preferred species of the claim are those disclosed in the intervening prior art publication.

For some reason, without this three part analysis, the concept that priority may be denied to a parent disclosure yet that parent disclosure may anticipate the daughter claim. Even as recently as 2012 a jurist with nearly thirty full years on the Federal Circuit was unable to grasp this concept:

"The panel majority forgets that 'matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application.' *Waldemar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed.Cir.1994); see *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1438 (Fed.Cir.1984) ('The earlier filing date of the parent application pertains to material in the C–I–P application also disclosed in the prior application. 35 U.S.C. § 120.'). Instead, the panel majority relies upon the common subject matter from the [parent] patent disclosure to invalidate the [daughter] claims supported by that subject matter. This is incorrect, for the common subject matter in the [daughter] patent is entitled to the [parent] filing date. That entitlement is not lost by issuance of the [parent] patent. The common subject matter, properly carried forward in copending continuing patents, cannot be prior art against itself, as the majority holds."

Santarus, Inc. v. Par Pharm., Inc., 694 F.3d 1344,1361-62 (Fed. Cir. 2012)(Newman, J., dissenting in part)

§ 11[f] *Steenbock* in the International Patent Arena

While claims in a parent (priority) application are not a necessary element for either domestic or foreign protection, providing a definition of the invention in the original Summary of the Invention that provides verbatim support for a later application provides the safest approach to protect the substantive priority right. Where there is an absence of such support open questions are raised in the international patent arena.

Particularly contentious is the question that arises where parent (priority) application is to a genus of a different scope than the genus of the later convention application. Indeed, within the European Patent Office, it took several years to

seemingly straighten out the law as to what constitutes the "same invention" for priority purposes. See *In re Same Invention*, Case G02/98, *sub nom In re Same Invention*, Case G02/98, sub nom "R. v. X/Same invention", [2002] E.P.O.R. 17 p. 167 (EPO Enlarged Bd. App. 2001, and "Requirement for Claiming Priority of the 'Same Invention'", Official Journal 413 (October 2001), referral by the President of the EPO, [1999] E.P.O.R. 503 (EPO Enlarged Board of Appeal 1998). The *Same Invention* opinion from 2001 concludes that "[t]he requirement for claiming priority of 'the same invention', referred to in Article 87(1) [of the European Patent Convention], means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole." Same Invention, pp. 25-26; emphasis added. For earlier debates on the subject, see Ulrich Joos, *Identität der Erfindung, Mehrfach- und Teilpriorität im europäischen Patentrecht*, 73 in Straus, ed., AKTUELLE HERAUSFORDERUNGEN DES GEISTIGEN EIGENTUMS — FESTGABE VON FREUNDEN UND MITARBEITERN FÜR FRIEDRICH-KARL BEIER ZUM 70. GEBURTSTAG (Carl Heymanns Verlag KG 1996); see also Richard L. Schwaab & Harold C. Wegner, *Harmonization and Priority of Invention* in AKTUELLE HERAUSFORDERUNGEN * * *, pp. 159-169 (1996); Ernest Guttmann, *Effects of Priority Rights on Claims of European Patents Claiming One or Several Priority Dates*, 22 INT'L REV. INDUS. PROP. AND COPYRIGHT L. 740 (1991); Friedrich-Karl Beier & Rainer Moufang, Convention Priority for Improvement Patents and Patents of Addition, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 593 (1990); Wegner, *Filing Evolutionary Inventions*

Abroad: Pitfalls under the Paris Convention, 23 INT'L REV. INDUS. PROP. & COPYRIGHT L. 184 (1992).

§ 11[g] **Inventorship Issues with Too Many Claims**

If a patent has, say, one hundred claims, it may be difficult to sort out who is the inventor of *each* claim. Incorrect – even innocent – failure to nominate the correct inventorship for *all* the claims may be fatal to an enforceable patent right

§11[g][1] **Difficulty to Sort out Inventorship with Many Claims**

An incorrect inventorship nomination even as to one claim may poison the value of the patent. If a third party inventor of even one claim who is not named as an inventor and who is not under an obligation to assign his rights to the patent applicant may be the basis for a defendant in a lawsuit to escape liability: If he is able to purchase the patent rights of the unnamed inventor of "claim 37" he will then have a defense to the charge of infringement. (And, of course, if there is a *willful* false nomination of inventorship then this raises the possibility of an inequitable conduct charge.)

§11[g][2] **The "Starting Off" Point**

It is important to know the inventor's "starting off" point to segregate the inventor's contribution from the previous work of others. Useful information is often provided by the inventor. The information about the prior work of others is useful to segregate the inventor's contribution from the prior art *and also from the inventive contributions of others.*

Consider the following example:

A coworker of the inventor has developed a new Framus system which comprises elements A, B, C, D and E.

The inventor has discovered an improved element D-plus, so that his invention is introduced into the coworkers system as a combination of elements A, B, C, D-plus and E.

What happens if the inventor fails to inform the patent attorney that the combination A,B,C, D and E is the invention of a third party (which may or may not be prior art under 35 USC § 102 as to the inventor)?

If the "starting off point, here, is given to the inventor, he will have no trouble making sure that every claim includes element D-plus, for example:

Claim 1: The combination A, B, C, D-plus and E.

Claim 2: The subcombination C,D-plus and E.

Claim 3: The element D-plus.

But, if the coworker's "starting off" point is not identified, then the following claims could be drafted based upon the inventor's disclosure of the preferred embodiment:

Claim 1: The combination A, B, C, D and E.

Claim 2: The subcombination C,D and E.

Claim 3: The subcombination A, B and C.

Here, claims 1 and 2 are clearly the coworker's invention.

If the work remains secret within the coworker's organization and is not public "prior art", then the coworker would need to be named as a coinventor.

If the coworker is not under an obligation to assign his invention to the applicant and is not named in the patent, then years later the coworker could sue to be named as a coinventor. Under United States patent law, a coinventor has the right to license or sell his rights to the patent if he is the inventor of *any claim* of the patent. This means that if there are claims to, for example, element-D that is the sole invention of the inventor-applicant, the presence of claims to inventions of the coworker permit the coworker to assign or license his rights to *all* claims of the patent to a stranger. *There is no requirement for a coinventor to obtain the consent of all coinventors to license or sell a coinventor's patent rights.*

(Litigation to settle this issue may occur after grant of the patent when the accused infringer discovers the mistaken inventorship: The accused infringer then buys the patent rights of the unnamed inventor and uses such rights as a defense to a charge of patent infringement.)

Providing information about the "starting off" point will go a long way toward avoiding inventorship nomination problems. Inventorship nomination, if false and not corrected, leads to invalidity of the patent right. If an omitted coinventor is located during patent litigation who is not under an obligation to assign patent rights to anyone, the accused infringer-defendant in the patent infringement lawsuit may purchase the unnamed coinventor's patent rights and use such rights as a defense to the charge of infringement.

§11[g][3] Coinventor Right to License the Patent Right

Incorrect inventorship is a common basis to defend a patent infringement suit. Assume that the Acme Widget Company is sued for infringement of claim 3 of the Smith patent owned by Framus Incorporated. But, claim 37 of the patent is discovered by Acme Widget Company to have been invented by Jones who was not (and is not) under an obligation to assign his patent rights to anyone.

Acme Widget Company then is able to purchase Jones' right as a coinventor of the patent and, if successful in having the inventorship changed to list Jones as a coinventor, Acme Widget Company is able to successfully defend the infringement suit.

The statutory basis for the right of a coinventor to license his patent rights *without* permission of the other coinventors and *without* sharing in the proceeds of the license is found in 35 USC § 262:

35 USC § 262. Joint owners . In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

The situation is explained in *Willingham v Lawton*, 555 F2d 1340, 1344 (6th Cir. 1977):

Co-owners of a patent have interests which are essentially distinct and separate. The nature of a patent is such that co-owners are at the mercy of each other. In the absence of a special agreement, each of the co-owners of a patent may make, use or sell the patented invention without accounting to the other owners. 35 U.S.C. § 262 (1952). It has been held that a co-owner of a patent can even grant a license to a third party without consent of the other owners and neither the co-owner-licensor nor the third-party-licensee is liable to the other owners. Talbot v. Quaker State Oil Refining, 104 F.2d 967 (3d Cir. 1939); Bendix Aviation Corp. v. Kury, 88 F. Supp. 243 (D.N.Y. 1950). See Aberdeen Hosiery Mills Co. v. Kaufman, 96 U.S.P.Q. 133 (S.D.N.Y. 1952). The unlimited use of a patent by one co-owner could effectively destroy the value of a patent to the other co-owner. Within this framework, a rule requiring all joint owners to participate in an infringement suit effectively precludes one owner from filing an harassing suit against another owner's licensee.

§11[g][4] Duty of Disclosure Issues for Inventorship

It is important in meeting the duty of disclosure that the inventor provide information to the patent attorney that will avoid a situation where the inventorship is incorrectly named. If the omission of the correct inventorship is *deliberate* there can be inequitable conduct implications. This is seen from *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 828 (Fed. Cir. 2010):

[W]hen named inventors deliberately conceal a true inventor's involvement, the applicants have committed inequitable conduct and the patent is unenforceable even as to an innocent co-inventor. *Frank's Casing Crew & Rental Tools, Inc. v. PMR Techs., Ltd*., 292 F.3d 1363, 1376-77 (Fed. Cir. 2002). In *Frank's Casing*, this court held that the named inventors committed inequitable conduct by deliberately excluding an innocent co-inventor from their patent application. *Id*. at 1376. The court explained that "if unenforceable due to inequitable conduct, a patent may not be enforced even by "innocent" co-inventors. One bad apple spoils the entire barrel. Misdeeds of co-inventors, or even a patent attorney, can affect the property rights of an otherwise innocent individual.'" *Id*. at 1377 (quoting *Stark* ***v.*** *Advanced Magnetics*., 119 F.3d 1551, 1556 (Fed. Cir. 1997)).

Accordingly, this court sustained the district court's holding of unenforceability. *Id*. The court, however, remanded the case "for the limited purpose of determining the correct inventorship" because an action under 35 U.S.C. § 256 did not "prevent [] a court from correcting the inventorship of an unenforceable patent." *Id*. at 1377 (alteration added).

As in *Frank's Casing*, the district court here had no obligation to resolve inventorship for the purposes of holding the patent unenforceable. If Mr. Bauer – as the sole named inventor – deliberately misrepresented that he invented the '773 patent's fastener to the PTO, his deceit would "spoil [ ] the entire barrel," leaving the '773 patent unenforceable. *Stark*, 119 F.3d at 1556 (alteration added). The only substantive difference between this case and *Frank's Casing* is that we have no reason here to remand to the district to resolve inventorship as no party has sought to correct inventorship under 35 U.S.C. § 256. Accordingly, the district court did not err by addressing inequitable conduct and unenforceability without resolving inventorship.

§ 12 Three Part Claim as the Default Claiming Choice

The most common and easiest claim form to use is the three part claim. The three part claim has a preamble, transition and body stating elements. The focus, here, is on this model where the claim is to the product:

[preamble]+[open transition]+[element(s)].

Any critical prior art-distinguishing feature should be recited as part of a claim element (as opposed to mere recitation in the preamble).

The simple product claim should be set forth as a set of elements with *no* important limitation found anywhere but in the elements themselves:

1. A [thing] comprising:
   [a] element A; and
   [b] element B.

There are basically three parts to a claim – the preamble, the transition and the elements.

§ 12[a] The Preamble as an Introduction

The preamble (all the wording before the transition – here, "comprising") should be an introduction to the invention set forth in the elements. Historically, some applicants have employed a drafting strategy where features that distinguish over the prior art are placed in the preamble as opposed to the elements. This strategy is vulnerable, however, to a patent validity trial a the Patent Trial and Appeal Board because of the "broadest reasonable interpretation" given to claims at such trials. *See* **§ 12[D],** *Preamble vs. Elements to Distinguish the Prior Art.*

§ 12[b] The Open Transition

The Open Transition should as a default be either "comprising" or "which comprises". This is an "open" transition that is interpreted to mean that the claim has coverage for any combination of the elements stated in the claim *and any combination also including unstated elements.* Thus, a claim to a combination "comprising A and B" includes a combination of A+B, *and* A+B+C. (Other transition forms are "closed" ("consisting of") or "hybrid" ("consisting essentially of") and are *not* recommended.)

§ 12[c] The Elements to Distinguish the Prior Art

The Elements represent the heart of the claim is the recitation of the elements which, taken together, must establish novelty and nonobviousness over the prior art.

§ 12[d] Preamble vs. Elements to Distinguish the Prior Art

If a critical limitation necessary to distinguish the prior art is found in the preamble that is not clearly stated in the recitation of elements, a claim interpretation *in a District Court* could very well lead to a conclusion *either* that the feature is not a limitation (leading to an invalidity ruling) *or* that that the feature *is* a limitation (leading to a ruling sustaining the patent). But, in either case, the issue is highly fact dependent and subject to an amorphous body of case law traced to *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.,* 868 F.2d 1251 (Fed.Cir.1989). No matter which answer would be given in a District Court, *both* answers often would be *reasonable.*

In a patent trial at the Patent Trial and Appeal Board, all that is necessary to invalidate a patent in this setting is a determination that the claim is *not* limited by the preamble as the "broadest reasonable interpretation" rule used at the Patent Office. *See* **§** 19[d], *Cabining the "Broadest Reasonable Interpretation"*

Determination whether a preamble constitutes a limitation to the scope of a claim is a fact-dependent issue: "Whether to treat a preamble term as a claim limitation is 'determined on the facts of each case in light of the claim as a whole and the invention described in the patent.'" *American Med. Sys. Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358-59 (Fed. Cir., 2010)(Bryson, J.)(quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed.Cir.2003)). ""No litmus test \defines when a preamble limits claim scope." *Catalina Marketing Intern. v. Coolsavings.Com*, 289 F.3d 801, 808 (Fed. Cir., 2002), quoting *Corning Glass*, 868 F.2d at 1257); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1347 (Fed. Cir., 2002)(Prost, J.)(same).

As explained in *Applied Materials*, "[w]hether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is *determined on the facts of each case* in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history." *Catalina Marketing Intern. v. Coolsavings.Com*, 289 F.3d 801, 808 (Fed. Cir., 2002)(quoting *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed.Cir.1996))(emphasis added). Thus, "[w]hether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[ ] ... patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" *Id.* (quoting *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed.Cir.1989)). In addition to the fact-specific nature of the inquiry, the guidance offered by the Federal Circuit is quite flexible and laced with generalities: "In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Id.* (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999)). Query: Precisely what, in legal terms, is meant by the "life, meaning, and vitality" of a claim?

§ 13. *Pennwalt* "All Elements" Claim Drafting Rule

The "all elements" rule has been a fixture of American patent law since the nineteenth century when formal claims were introduced. It has been a bedrock principle of the Federal Circuit since *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed. Cir. 1987) (en banc),

The "all elements" rule is explained in *TecSec, Inc. v. IBM Corp*., 731 F.3d 1336 (Fed.Cir. 2013)(Reyna, J., dissenting). Thus:

"Under the 'all elements' rule, the accused device must contain each limitation of the claim, either literally or by an equivalent, to be infringing. *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc*., 529 F.3d 1364, 1379 (Fed. Cir. 2008) (quoting *Freedman Seating Co. v. Am. Seating Co*., 420 F.3d 1350, 1358 (Fed. Cir. 2005)). Most often, the 'all elements' rule serves to prevent vitiation of a claim limitation when the infringement theory is based on the doctrine of equivalents, but that is not the case here. *Trading Techs. Int'l, Inc. v. eSpeed, Inc*., 595 F.3d 1340, 1355 (Fed. Cir. 2010) (quoting in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co*., 520 U.S. 17, 39 n.8 (1997)); *see also TIP*, 529 F.3d at 1379; *Freedman*, 420 F.3d at 1358; *Pennwalt Corp. v. Durand-Wayland, Inc*., 833 F.2d 931, 949-50 (Fed. Cir. 1987) (en banc) (Nies, J., additional views). Relevant to this case, literal infringement 'occurs when every limitation recited in the claim appears in the accused device, i.e., when 'the properly construed claim reads on the accused device exactly.' *Demarini Sports v. Worth*, 239 F.3d 1314, 1331 (Fed. Cir. 2001) (quoting *Amhil Enters., Ltd. v. Wawa, Inc*., 81 F.3d 1554, 1562 (Fed. Cir. 1996))."

TecSec, 731 F.3d at 1351 n.2.

The "all elements" rule is quite simple. If an invention has parts [A], [B] and [C], a claim reciting *all* of the elements [A], [B] and [C] is directly infringed *only* if the competitor practices the same invention with *all* of the elements [A], [B] and [C].

This means that if element [B] is *not* critical to the invention, a third party may avoid the patent entirely simply by practicing the otherwise same invention with only elements [A] and [C] with deletion of the nonessential element [B].

Thus, contrary to the wishful thinking of some, if there is a claim to a combination of elements that includes an "unimportant" element that does not impact the overall result of an invention, a finding of infringement requires that "all elements" be present. There is no basis to find infringement where a competitor precisely copies the "gist" of the invention and the "important" elements *if any unimportant element of the claimed combination (or its equivalent) is eliminated.*

§ 13[a] Nineteenth Century Foundation of the "All Elements" Rule

There is a rich history of precedent more from more than one hundred years ago that established the rule. Justice Story applied the "all elements" rule nearly 200 years ago in *Barrett v. Hall,* 2 F.Cas. 914 (No. 1047)(D. Mass. 1818)(Story, J.). Justice Story explained that "the patent [is] for the combination only[;] it is no infringement of the patent to use any of the machines separately, if the whole combination be not used; for in such a case the thing patented is not the separate machines, but the combination; and the statute gives no remedy, except for a violation of the thing patented." *Barrett v. Hall,* 2 F.Cas. at 924.

To be sure, a narrow focus on Federal Circuit precedent is basis to imagine that the doctrine should be traced to *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931 (Fed.ir.1987) (*en banc*)(Bissell, J.).

Yet, a simple review of *Pennwalt* manifests numerous cases from the Supreme Court each dating back more than one hundred years. *See Pennwalt*, 833 F.2d at 949-51 (Nies, J., additional views)(citing *Prouty v. Draper*, 41 U.S. (16 Pet.) 335 (1842); *Brooks v. Fiske*, 56 U.S. (15 How.) 211, —219 (1853); *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Eames v. Godfrey*, 68 U.S. (1 Wall.) 78, 79 (1864); *Gould v. Rees*, 82 U.S. (15 Wall.) 187 (1872); *Dunbar v. Myers*, 94 U.S. (4 Otto) 187, 202 (1876); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 335-37 (1879); *Case v. Brown*, 69 U.S. (2 Wall.) 320, 327-28 (1864); *Gill v. Wells*, 89 U.S. (22 Wall.) 1, 26-30 (1874); *Fuller v. Yentzer*, 94 U.S. (4 Otto) 288, 297 (1876); *Gage v. Herring*, 107 U.S. (17 Otto) 640, 648 (1882); *Fay v. Cordesman*, 109 U.S. 408, 420-21 (1883); *Rowell v. Lindsay*, 113 U.S. 97, 102 (1885); *Sargent v. Hall Safe & Lock Co.*, 114 U.S. 63, 86 (1885); *Brown v. Davis*, 116 U.S. 237, 252 (1886); *Yale Lock Mfg. Co. v. Sargent*, 117 U.S. 373, 378 (1886); *McClain v. Ortmayer*, 141 U.S. 419, 425 (1891); *Wright v. Yuengling*, 155 U.S. 47, 52(1894); *Black Diamond Coal Mining Co. v. Excelsior Coal Co.*, 156 U.S. 611, 617-18 (1895); *Cimiotti Unhairing Co. v. American Fur Ref. Co.*, 198 U.S. 399, 410 (1905)).

More than twenty years after Justice Story spoke in *American Fur Ref. Barrett v. Hall*, he once again explained the "all elements" rule:

"The plaintiffs' patent is for an entire combination of all the three things, and not for a combination of any two of them. A patent for a combination of A, B and C, cannot be technically or legally deemed at once a combination of A, B and C, and of A and B alone."

Prouty v. Draper, 20 F.Cas. 11, 12 (No. 11,446) (D. Mass. 1841)(Story, J.), *aff'd,* 41 U.S. (16 Pet.) 336 (1842)(Taney, C.J.).

The Supreme Court in the *Eames* case rephrased the test for infringement: "[T]here is no infringement of a patent which claims mechanical powers in combination unless all the parts have been substantially used. The use of a part less than the whole is no infringement." *Eames*, 68 U.S. (1 Wall.) at 79 (1864).

Fifteen years later the doctrine was once again explained: "It is a well-known doctrine of patent law, that the claim of a combination is not infringed if any of the material parts of the combination are omitted. ***" *Water-Meter v. Desper*, 101 U.S. (11 Otto) at 335-37.

§ 13[b] *Pennwalt* Refinement of the "All Elements" Rule

Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931 (Fed. Cir. 1987) (en banc), is the leading case from the Federal Circuit on the "all elements" rule.

The implications of the *Pennwalt* "all elements" rule may be seen from the following hypothetical discussion based upon actual claim 1 of the case itself:

"1. An automatic sorting apparatus comprising

"[1] conveyance means for transporting a plurality of items to be sorted along a track and having individual cups for transporting each said item, said individual cups being connected in a continuous belt,

"[2] electronic weighing means incorporated into a portion of said track for generating a signal proportional to the weight of said item to be sorted,

"[3] reference signal means for providing a predetermined number of reference signals, the value of each signal established according to a predetermined criteria,

"[4] comparison means for comparing the signal generated by said electronic weighing means to the reference signals provided by said reference signal means,

"[5] clock means for incrementally signalling changes in position of an item to be sorted,

"[6] first position indicating means responsive to the signal from said clock means and the signal from said comparison means for generating a signal indicative of the position of the item to be sorted, and

"[7] discharge means responsive to the signal generated by said position indicating means for discharging the item to be sorted at a predetermined position."

If one as an initial draftsman is putting together a case for a fruit sorter as in *Pennwalt,* is this claim too broad? Too narrow? The answer depends upon the state of the prior art and the purpose of the claim. If the only patentable novelty of the invention is found in the combination of all seven elements, then the claim is as broad as can be drafted.

But, if it appears on drafting the application that a fruit sorter with element [2], *alone,* establishes patentable novelty, then the claim is far too narrow *as a generic claim.* (Then, the generic claim should cover only the fruit sorter with the improvement of element [2].) But, if the object is to capture a copyist who is providing a fruit sorter *with all seven elements,* then claim 1 is far better than any broader claim: It will be far easier to defend against an invalidity attack because the narrower the claim the more difficult it will be to establish.

§ 13[c] *Pennwalt,* Recent Case Law

The "all elements" rule of *Pennwalt* reflects the decisional law of the Supreme Court. See *Unidynamics Corp. v. Automatic Products Intern., Ltd*., 157 F.3d 1311, 1322 (Fed. Cir. 1998)(Rich, J.)(referring to "the Supreme Court's all-elements rule as enunciated in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997)[.]"). As explained by a former Chief Judge of the Federal Circuit in *Athletic Alternatives, Inc. v. Prince Mfg., Inc*., 73 F.3d 1573, 1581-82 (Fed. Cir. 1996)(Michel, J.):

"As we have often observed, *** the doctrine of equivalents is not a license to ignore or 'erase ... structural and functional limitations of the claim,' limitations 'on which the public is entitled to rely in avoiding infringement.' *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed.Cir.1987). Liability for infringement thus requires, without exception, that an accused product contain each limitation or its equivalent [which principle has been called the 'all limitations' or 'all elements' rule.] *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 398 (Fed.Cir.1994); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed.Cir.1987) ([e]n banc)[ ]."

§ 13[d] *Pennwalt* "All Elements" Claim Rule in Actual Practice

The *Pennwalt* rule has already been discussed in the context of traditional mechanical technologies earlier in this paper. This section deals with the practical realities of *Pennwalt:*

§ 13[d][1] "Minimum Elements" Rule, Flip Side of the "All Elements" Rule

The minimum number of elements *necessary* to define novelty and nonobviousness should be set forth in the generic claim. This is just another way of saying that the "all elements" rule of the *Pennwalt* case mandates a conclusion of noninfringement if one of the elements of a claim is missing in the accused embodiment.

Thus, fundamental to any understanding of *why* there should be claims to a limited number of elements of a combination is a detailed appreciation for the nuances of the *Pennwalt* case.

§ 13[d][2] Value of Having both Broad *and* Narrow Claims

The narrow claim in *Pennwalt* the may be valuable against a competitor who is copying *all* elements of that claim. This claim will be better than a generic claim in an enforcement proceeding because it is more difficult to invalidate a very specific claim with many elements than a broader claim. Yet, the broad claim is also important to guard against a copyist who wants to modify the technology to avoid the claims.

§ 13[d][3] *Limelight* Single Actor Performs "All Elements"

Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111 (2014), demonstrates the need to pay careful attention to the "all elements" rule in the context of internet claiming.

It is taken for granted in traditional technologies that a claim to a combination of elements is *directly* infringed a single actor. For example, if there is a Widget that has parts [a], [b] and [c], and the claim calls for the combination of elements [a], [b] and [c] the wholesaler, the manufacturer and the end user each practices the patented combination by making, using or selling the combination.

The situation gets tricky in the case of an internet process claim where a claim to a combination of steps may involve multiple parties. For example, Customer [A] may enter a series of keystrokes at Remote Terminal T_1 that sends an electronic signal to Headquarters Terminal T_2 which houses a central computer that "crunches" the information that then results in an instantaneous transmission from Headquarters Terminal T_2 to Customer [A] at Remote Terminal T_1:

In narrative fashion we have the situation:

Step One: Customer [A] enters a series of keystrokes at Remote Terminal T1 to Headquarters Terminal T2

Step Two: Headquarters Terminal T2 electronically sends information to Customer [A] at Remote Terminal T1.

If one now crafts a claim as a narrative of what happens in this process there is no single actor performing "all elements" of process.

Narrative Claim:
A process which comprises:
(a) Customer [A] enters a series of keystrokes at Remote Terminal T1 to Headquarters Terminal T2 ; and
(b) Headquarters Terminal T2 electronically sends information to Customer [A] at Remote Terminal T1.

Here, each party performs one step but not all steps of the claimed invention so there is no single direct infringer. Instead, the claim must be reworked so that a single actor performs all steps of the claim.

Single Actor (Customer [A]) Claim: A process which comprises:
(a) Customer [A] enters a series of keystrokes at Remote Terminal T1 to Headquarters Terminal T2 ; and
(b) Customer [A] at Remote Terminal T1 receives electronic information from Headquarters Terminal T2 .

Now, we have Customer [A] as a direct infringer who performs all steps of the claimed invention. Liability attaches to the Headquarters for active inducement under 35 USC § 271(b).

Single Actor (Remote Terminal T1) Claim:
A process which comprises:
(a) Headquarters Terminal T2 electronically receives from Customer [A] a series of keystrokes from Remote Terminal T1 ; and

(b) Headquarters Terminal T2 electronically sends information to Customer [A] at Remote Terminal T1..

Which of the two claims is better? Which should be chosen?

The answer is that both sets of claims should be chosen.

Both parties can now be found liable for direct infringement.

That *Limelight* is, indeed, really a question of the "all elements" rule is explained by Circuit Judge Linn:

Direct infringement liability requires that one actor performs each and every element or step of a claim. *See Aro* [*Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 340 (1961)] ("The patent is for a combination only. Since none of the separate elements of the combination is claimed as the invention, none of them when dealt with separately is protected by the patent monopoly." (quoting *Mercoid I*, [*Mercoid Corp. v. Mid–Continent Inv. Co.*, 320 U.S. 661, 667 (1944)])). Unlike indirect infringement under § 271(b) and (c), which both require a certain mens rea, *Global–Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060. 2068 (2011), under § 271(a), direct infringement is a strict-liability offense, *id.* at 2065 n. 2 ("Direct infringement has long been understood to require no more than the unauthorized use of a patented invention.... [A] direct infringer's *knowledge or intent is irrelevant.*" (emphasis added)). Because of the strict-liability nature of direct infringement, this court has limited direct infringement liability "to those who practice each and every element of the claimed invention," *BMC* [*Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1381 (Fed.Cir.2007)], i.e., the "single entity rule." *See Cross Med. Prods. v. Medtronic Sofamor Danek*, 424 F.3d 1293, 1311–12 (Fed.Cir.2005) (applying the single entity rule).

The single entity rule, consistent with the statute, protects an actor who practices less than all elements of a claim—i.e., does not practice the "patented invention"—from direct patent infringement liability.

The legislative history supports the single entity rule for direct infringement. Congress enacted § 271 to clarify the scope of *indirect infringement,* and in so doing, "left intact the entire body of case law on direct infringement." *Aro,* 365 U.S. at 342. When the Supreme Court held in Aro that § 271(a) did not change the law of direct infringement, the Court was referring to the single entity, all elements rule of direct infringement that was "well settled" in 1952. See Wallace v. Holmes, 29 F. Cas. 74, 80 (C.C.D.Conn.1871) ("The rule of law invoked by the defendants is this—that, where a patent is for a combination merely, it is not infringed by one who uses one or more of the parts, but not all, to produce the same results.... *This rule is well settled, and is not questioned on this trial.*" (emphasis added)).

Akamai Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301, 1347 (Fed. Cir. 2012)(en banc)(Linn, J., joined by Dyk, Prost, O'Malley, JJ., dissenting), *rev'd, Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014).

§ 13[d][4] Japanese Leadership on the *Limelight* Issue

The *Limelight* issue may have been new to domestic circles but much earlier there had been extensive discussions of the issue in Japan. Comparative studies date back to the writer's participation in 2001 SOFTIC Symposium, an international conference held in Tokyo just after the turn of the century, hosted by a quasi-governmental group, SOFTIC. The symposium included a detailed study of the question of infringement of multi-step internet method claims involving the participation of differing parties. It featured members of the judiciary including the Hon. Jan H.P. Willems, Judge, Boards of Appeal, European Patent Office and former Circuit Judge Randall R. Rader Federal Circuit; several leading Japanese authorities, Yoshio Kumakura, Attorney at Law; Shigeo Takakura, then-Director, Japan Patent Office; Masato Doauchi, Professor of Law, Tokyo University; and Naoki Mizutani, Attorney at Law; as well as American lawyers, David J. Kappos, then Assistant General Counsel, IBM Asia/Pacific; and this writer.

The discussion of joint infringement is reported in the Proceedings (pp. 82-100) on the SOFTIC website. The background for the issue of "all elements" infringement of multi-step internet method claims is available on the same website. H. Wegner, *E-Business Patent Infringement: Quest for a Direct Infringement Model.*

§ 13[e] Simple Claims to an Element or Small Subcombination

§ 13[e][1] Search for the Key Element

In an ideal situation, *one* element of the invention will be critical to distinguish the invention from the prior art. If this one element is also *critical* to practice of the invention, then this is the key single element that must be claimed *as such.* Then, anyone modifying the invention who nevertheless retains the use of this one element will be an infringer.

§ 13[e][2] Generalization of the Key Feature

Even if the key element is found in a single claim, standing alone, this is not sufficient for literal protection if there are equivalents that can be practiced. If an element can be *generalized* then "claim 1" should be thusly generalized. For example, if there is a "screw" that is part of a patentable element, it is advisable to have claim 1 refer to a "fastener" with a screw being in a subclaim.

§ 13[e][3] A Reasonable Number of Subclaims

Each claim is independently enforceable, so that if "claim 1" is found invalid then "claim 2" may be independently enforced. It is therefore important to have

claims drafted that cover commercially important areas that have some basis for enforcement independent from claim 1.

§ 13[e][4] Features Establishing Independent Basis for Patentability

If there are plural features of the principal embodiments that *each* establish nonobviousness of an invention, then the patentee with a "claim 2" that has this additional strength will have a better chance of successful enforcement against the user of a "claim 2" embodiment.

§ 13[e][5] Commercial Embodiments, *Per se,* and Unexpected Results

Often, the commercial embodiment has unexpected results that may tilt the balance in favor of patent validity. If a claim is not *limited* to that commercial embodiment, it is possible that the patentee may not be able to most effectively rely upon the unexpected results to confirm the validity of the claim in litigation.

All limitations that are *necessary* to distinguish over the prior art should be found as an element (or elements) which follow the transition.

§ 14 Jepson ("Improvement") Claims

A "Jepson claim" is a combination claim to focus on a novel improvement. The terminology stems from the petitioner in the *Jepson* case nearly a century ago. *Ex parte Jepson*, 1917 Com'r .Dec. 62 (Ass't.Comm'r.Pat.1917). The Jepson claim has three parts, *first,* a preamble describing the prior art; *second,* a transition phrase (e.g., "wherein the improvement comprises"); and *third,* the elements of the invention constituting the improvement.

§ 14[a] PTO Sanctioned Claim Format

The Jepson claim has been codified in the *Rules of Practice in Patent Cases* as 37 CFR § 1.75(e):

"Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:

"(1) A *preamble* comprising a general description of all the elements or steps of the claimed combination which are conventional or known,

"(2) A [*transition*] *phrase* such as "wherein the improvement comprises," and

"(3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion."

As stated in the *Manual:* "[t]he form of claim required in 37 CFR 1.75(e) is particularly adapted for the description of improvement-type inventions. It is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination." MPEP § 608.01(m), *Form of Claims.*

§ 14[b] Jepson Preamble as an Admission of Prior Art

"[In *In re Fout*, 675 F.2d 297, 300, 301 (CCPA 1982)], an applicant's admission of actual knowledge of the prior invention of another, which was described in the preamble of a Jepson claim, was held to constitute an admission that the described invention was prior art to the applicant." *Riverwood Int'l Corp. v. R. A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003)(Linn, J.).

As explained by the Patent Office the Jepson preamble is viewed as an admission of prior art status for everything stated in the preamble:

"Drafting a claim in Jepson format (i.e., the format described in 37 CFR 1.75(e); see MPEP § 608.01(m)) is taken as an implied admission that the subject matter of the preamble is the prior art work of another. *In re Fout*, 675 F.2d 297, 301 (CCPA 1982) (holding preamble of Jepson-type claim to be admitted prior art where applicant's specification credited another as the inventor of the subject matter of the preamble). However, this implication may be overcome where applicant gives another credible reason for drafting the claim in Jepson format. *In re Ehrreich*, 590 F.2d 902, 909-910 (CCPA 1979) (holding preamble not to be admitted prior art where applicant explained that the Jepson format was used to avoid a double patenting rejection in a co-pending application and the examiner cited no art showing the subject matter of the preamble). Moreover, where the preamble of a Jepson claim describes applicant's own work, such may not be used against the claims. *Reading & Bates Construction Co. v. Baker Energy Resources Corp*., 748 F.2d 645, 650 (Fed. Cir. 1984) ; Ehrreich, 590 F.2d at 909-910."
MPEP § 2129, *Admissions as Prior Art*, ¶ III, *Jepson Claims.*

*Pentec, Inc. v. Graphic Controls Cor*p., 776 F.2d 309 (Fed. Cir. 1985)(Markey, C.J.), provides an explanation where the Jepson claim form was used:

[The patentee] contends that the district court did not consider the claimed invention as a whole pursuant to § 103, see *Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 785, 218 U.S.P.Q. (BNA) 698, 700 (Fed. Cir. 1983), i.e., that the court … improperly separated the preamble from the improvement clause of the Jepson claim. Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, see *In re Ehrreich*, 590 F.2d 902, 909-10 (CCPA 1979); 37 C.F.R. § 1.75(e)(1984), unless the preamble is the inventor's own work, *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 649, 223 U.S.P.Q. (BNA) 1168, 1172 (Fed. Cir. 1984), the claimed invention consists of the preamble in combination with the improvement, see Manual of Patent Examining Procedure § 608.01(m) (5th ed. 1983).

Pentec v. Graphic Controls, 776 F.2d at 315 (citations omitted).

§ 14[c] Negative Impression on the Scope of Patentability

Even without considering whether the preamble of a Jepson claim is an admission of prior art status for the preamble, the Jepson claim format suggests a narrow improvement invention.

Consider the following scenario where the invention consists of elements A, B, C, D and E and the improvement is the provision of element D^i.

A traditional (non-Jepson) claim would read, for example:

"A combination which comprises:
(a) Element "A";
(b) Element "B"'
(c) \Element "C";
(d) Element "D^i"; and
(e) Element "E".

Now, consider a Jepson claim to the same invention:

In the combination of elements "A", "B", "C", "D" and "E", the improvement which comprises "Element D" being Element "D^i".

To a lay patent person (e.g., a typical trial judge without patent background) the superiority of the regular (non-Jepson) claim should be apparent. Noted Professor Janice Mueller counsels the patent draftsman to "[t]ry to avoid *Jepson* ... claims. Patent examiners understand what … specialized claiming formats signify, but judges and juries will not. A long *Jepson*-format preamble only furthers the impression that the claimed subject matter is merely a minor addition to old technology rather than a pioneering advance entitled to broad protection." Janice M. Mueller, *Crafting Patents For The Twenty-First Century: Maximize Patent Strength and Avoid Prosecution History Estoppel in a Post-Markman/Hilton Davis World*, 79 J. Pat. [& Trademark] Off. Soc'y 499, 504 (1997)

§14[d] An Examiner Favors the Jepson Claim Format

As seen from the example shown in the previous section, it is far, far easier for the Examiner to search and examine a Jepson claim than a regular three part (non-Jepson) claim. Currying favor with the Examiner comes at a price: Do the admissions created by the Jepson preamble make it more difficult to obtain grant of a patent on the merits of nonobviousness of the invention? Will the admissions served to destroy the nonobviousness of an invention in a trial court litigation? It is, of course, easy to see that the Examiner will invariably favor presentation of a Jepson claim. A professor with many years of experience in the classroom concludes that "[e]xperience teaches [Examiners] that Jepson claims are far more readily parsed and compared to prior art than other claim formats." John R.

Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 Berkeley Tech. L.J. 727, 756 (2002).

§14[e] European "Characterized by" (*dadurch gekennzeichnet*) Claims

The German "dadurch gekennzeichnet" or "characterized by" claim of the European Patent Office has seeming similarities to the Jepson claim.

It is dangerous to look to superficial similarities and then conclude that the same claim form is used in Europe and the United States.

§14[e][1] European "Two Part" Claim is Different from Jepson

There are clear differences between the various American "Jepson" claim form and the European "two part" or "characterized by" claim. Specific provision for the European "two part" claim is found in EPO Rule 43(1):

"The claims shall define the matter for which protection is sought in terms of the technical features of the invention. Wherever appropriate, claims shall contain:
"(a) a statement indicating the designation of the subject-matter of the invention and those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, form part of the prior art;
"(b) a characterising portion, beginning with the expression 'characterised in that' or 'characterised by' and specifying the technical features for which, in combination with the features stated under sub-paragraph (a), protection is sought."

The European practice is explained by the European Patent Office in its official guidelines:

"Rule 43(1)(a) and (b) define the two-part form which a claim should have 'wherever appropriate'. The first part should contain a statement indicating 'the designation of the subject-matter of the invention' i.e. the general technical class of apparatus, process, etc. to which the invention relates, followed by a statement of 'those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the prior art'. This statement of prior-art features is applicable only to independent claims ***. It is clear from the wording of Rule 43 that it is necessary only to refer to those prior-art features which are relevant to the invention. For example, if the invention relates to a photographic camera but the inventive step relates entirely to the shutter, it would be sufficient for the first part of the claim to read: 'A photographic camera including a focal plane shutter' and there is no need to refer also to the other known features of a camera such as the lens and view-finder. The second part or 'characterising portion' should state the features which the invention adds to the prior art, i.e. the technical features for which, in combination with the features stated in sub-paragraph (a) (the first part), protection is sought.

"If a single document in the state of the art according to Art. 54(2), e.g. cited in the search report, reveals that one or more features in the second part of the claim were already known in combination with all the features in the first part of the claim and in that combination have the same effect as they have in the full combination according to the invention, the examiner should require that such feature or features be transferred to the first part. Where, however, a claim relates to a novel combination, and where the division of the features of the claim between the prior-art part and the characterising part could be made in more than one way without inaccuracy, the applicant should not be pressed, unless there are very substantial reasons, to adopt a different division of the features from that which he has chosen, if his version is not incorrect.

"If the applicant insists on including more features in the preamble than can be derived from the closest available prior art, this should be accepted. If no other prior art is available, such a pre-characterising portion could be used to raise an objection on the ground of lack of inventive step."

Guidelines for Examination, Part F, Ch. IV, § 2.2, *Two-part form* (European Patent Office 2015)(http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_2_2.htm)
Rule 43(1)

§ 14[e][2] Japan Usage of Improvement Claims

It has been suggested that a United States priority application for purposes of a later Japan Paris Convention filing one should provide claims in the European *dadurch gekennzeichnet* ("characterized by") or the American "Jepson claim" form, because (under this theory) this will pave the way for usage of such formats particularly for Japan.

According to the Japan Patent Attorneys Association neither the use of the European *dadurch gekennzeichnet* ("characterized by") nor the American "Jepson claim" will provide a broader scope of protection in a patent infringement litigation vis a vis a traditional claim format:

"There is no particularly preferred claim format [in Japan]. Even if a Jepson type claim format is used, the technical scope of the claim must be determined with consideration of the preamble, since the preamble constitutes a part of the invention. There is no difference in the scope of protection of claims between different types of claims. There would be no form which is more easily interpreted by the court."

Kenji Asai, Kanji Fujiyoshi, Fujihiro Kanda, Shuhei Katayama, Yoshihiko Kido, Shinichi Kimura, Hiroshi Kobayashi, Tomoya Kurokawa, Takao Matsui, Takanori Nakajima, Nobuyuki Nishikawa, Takeshi Nonaka, Toshiharu Ogawa, Makoto Onda, Yoko Sakuma, Takahisa Satoh, Yasumitsu Suzuki, Yukihisa Tamakushi, Yoshikazu Tani, Hitoshi Wada, Masashi Yanagida and Tamaki Yoshida, *Questions and Answers Regarding Japanese Patent Practic*e, Answer A11 to Question 11: "Is one particular claim format (for example, European 'characterized' format, Jepson [claim], etc.) preferred to increase chances of an expanded claim interpretation in subsequent litigation?" , Japan Patent Attorneys Association**,** International Activities Committee (3rd ed. 2007).

§ 15. Claiming Patent-Eligible Subject Matter

It must always be kept in mind that this book is focused upon drafting the first application "today" which – in the case of many areas of patent-eligibility concerns – will be first examined "tomorrow", which means an examination under a new Administration that may very well have different policies on examination of subject matter now under attack on the basis of patent-eligibility under 35 USC § 101. Many changes may – or may not – take place in the time interval between the filing "today" and the examination "tomorrow". *See* § 1[b][7], *New Approach in a New Administration in 2017* (discussing options open under a more patent-friendly Under Secretary of Commerce).

"Inventive" applications of software and biotechnology innovations as well as diagnostic methods have come under special scrutiny under 35 USC § 101 through a series of cases denying patent-eligibility starting with *Bilski* v. *Kappos*, 561 U.S. 593 (2010)(software), and continuing with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(diagnostic method); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107, 2116 (2013)(DNA); and *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software). Undoubtedly the most extreme denial of patent-eligibility based upon *dicta* in *Mayo* is *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __(Fed. Cir. 2015)(Reyna, J.).

In view of the case law, how should one claim and provide supporting disclosure for innovative software that is considered "abstract"? For an invention involving a combination of elements including a product of nature? A derivative of a product?

For a *first* patent application drafted "today", it is important to draft a *disclosure* that will support a wide variety of claims that may be the most apt way of defining the invention based upon the evolving standards of patent-eligibility that will be in force through case law modifications "tomorrow", the time three or so years down the road when the application will be first examined.

The Patent Office *does* provide guidance on patent-eligibility, but following such guidance for drafting a patent application is dangerous. Such guidance is relatively unimportant in drafting a specification "today", because the case law is certainly in a fluid, moving shape that will change over time. In a sense, Patent Office guidance is a negative double whammy: To the extent that an applicant targets his specification and claims today to confirm to Patent Office guidance and that guidance is *too liberal vis a vis* the case law, an opponent can challenge the grant at the Patent Trial and Appeal Board in a Post Grant Review. If the guidance is *too strict* an applicant following this guidance shortchanges his patent position. Therefore, attention is focused in this book on the statute, rules and case law, and not on such Patent Office guidance.

In considering patent-eligibility under 35 USC §101 it must be remembered that the focus of this book is on drafting a *first* filing, "today", the likely priority application for a final application that will be examined "tomorrow", several years from now. Even if this first filing turns out to be the *only* application that will be examined, the first action in the application is likely to take place three or more years down the road: At that time, "tomorrow", the patent-eligibility law will undoubtedly be more moderate than the current state of the law where we may be at the point of the ultimate swing of the patent-eligibility pendulum to the dark side, away from patent-eligibility. Overall, in an historical overview of the law of patent-eligibility since the early seventeenth century Statute of Monopolies, the current mini-era of anti-patent challenges is just five years old, starting with the infamous Supreme Court *Bilski* decision: The pendulum *will* swing back, away from the extreme result recently reached in *Ariosa*. *See* § 15[a], *Patent-Eligibility Law in a State of Flux.*

Ariosa presents perhaps the best example where a claim *is* (or *should be*) patent-eligible, but falls short by the rigid *dicta* in *Mayo.* The invention in *Ariosa* permits DNA testing of a fetus *without* invasive sampling of amniotic fluid: This is accomplished by drawing a maternal blood sample and *amplifying* its DNA content through polymerase chain reaction so that what would otherwise be a *de minimus* amount of DNA that could not be tested, instead permits DNA testing of the maternal blood for foetal DNA content. It is impossible to consider the invention in *Ariosa* as anything short of pioneer, and most certainly a nonobvious invention or – in the words of the Supreme Court patent-eligibility cases – one that has an "inventive step". Yet, dissecting the claims in *Ariosa* and following *Mayo* has led to a conclusion that the claims lack patent-eligibility under 35 USC § 101.

Undoubtedly, if *Ariosa* were to gain *certiorari* the case would represent a strong challenge to the scope of *Mayo*. *Id.*

Given the uncertainties of how the law will evolve in the coming years, how should a specification be drafted today to account for such changes? In the context of drafting a first, priority filing, the challenge for "today" is to draft a first application that will be in a position for favorable examination "tomorrow". As for any invention, it is important to identify an "inventive" feature – what is nonobvious under 35 USC § 103. Then, the disclosure for the application to be filed "today" should include every detail of the environment of that inventive feature. The immediate goal is to provide *support* for whatever claim may be best suited to the patent-eligibility law of "tomorrow", at a time when the application will be examined and at a time when support will be needed for claims yet to be drafted. *See* § 15[b], *Disclosure "Today" as Basis for Claims "Tomorrow."*

When drafting a claim where an element is either an "abstract" feature or is derived from a "natural" product it is important to provide basis for a combination keyed to an "inventive" feature, whether that is a specific element or subcombination or the invention "as a whole". This will provide basis at a later date for drafting a combination claim that accentuates the inventive feature. *See* § 15[b][1], *Combination Definition Integrating an Inventive Feature*. The inventive feature should be integrated as an essential feature of the combination. *See* § 15[b][2], *Pinpointing the Inventive Feature in a Combination Claim.* Care must be taken to demonstrate the integral nature of a combination invention and to thus focus on the inventiveness – nonobviousness – of the claimed invention *as a whole. See* § 15[b][3], *"Conventional" Element vs. Combination "As a Whole".*

As an example of a successful approach consider a "Diehr claim". *See* § 15[b][4], *Diehr vs. a Simplistic "Apply it" Claim Approach.*

§ 15[a] *Ariosa*, Patent-Eligibility Law in a State of Flux

The majority opinion in *Ariosa* demonstrates just how far the Federal Circuit has interpreted the dicta from *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), to the point that the Federal Circuit runs counter to other Supreme Court precedent such as the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966), as well as its own precedent such as *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995), and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996).

In *Ariosa* the majority issued perhaps its most extreme application of *dicta* in *Mayo* to deny patent-eligibility of truly "inventive" subject matter where it was now possible to test for genetic conditions in a fetus simply by drawing blood from the mother without invasive testing of an amniotic fluid sample, a most remarkable breakthrough discovery. "In 1996, [the patentees] Drs. Dennis Lo and James Wainscoat discovered cell-free fetal DNA [ ] in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. [Cell-free fetal DNA] is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman." *Ariosa*, __ F.3d at __.

The minute amount of fetal DNA in the mother's bloodstream could not have been basis for genetic testing years ago, but with the discovery that minute amounts of such fetal DNA are present in the maternal bloodstream permitted use of "polymerase chain reaction ("PCR") [which is] a widely used technique in

molecular biology that was invented by Kary Mullis in 1983. Indeed, in 1993, Mullis won the Nobel Prize in Chemistry for his development of PCR[.]" *Carnegie Mellon University v. Hoffmann-La Roche, Inc.*, 541 F.3d 1115, 1129 n.4 (Fed. Cir. 2008).

Claim 1 of the patent in *Ariosa* is to "[a] method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises [(a)] *amplifying a paternally inherited nucleic acid* from the serum or plasma sample[;] and[(b)] detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample." *Ariosa*, __ F.3d at __ (emphasis added).

The extreme nature of *Ariosa* is explained in the concurring opinion by the elder member of the panel:

"*** I am bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012). In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

"It has long been established that '[l]aws of nature, natural phenomena, and abstract ideas are not patentable.' *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (citations omitted). In *Mayo*, the Supreme Court set forth a two-step framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. The first step looks to determine whether claims are directed to a patent-ineligible concept. *Mayo*, 132 S. Ct. at 1297. If they are, the second step is to consider whether the additional elements recited in the claim 'transform the nature of the claim' into a patent-eligible application by reciting an 'inventive concept' that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.' *Id*. at 1294.

"In applying the second part of the test, the Supreme Court in *Mayo* discounted, seemingly without qualification, any '[p]ost-solution activity that is purely conventional or obvious,' *id*. at 1299 (original alterations omitted). This was unnecessary in *Mayo*, because doctors were already performing in combination all of the claimed steps of administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels, *id*.

"In *Diamond v. Diehr*, the Supreme Court held that 'a new combination of steps in a process may be patentable even though all the constituents of the combination were well-known and in common use before the combination was made.' 450 U.S. 175, 188 (1981). As *Mayo* explained: *Diehr* 'pointed out that the basic mathematical equation, like a law of nature, was not patentable. But [*Diehr*] found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole.' *Mayo* 132 S. Ct. at 1298. Despite that recognition, *Mayo* discounted entirely the 'conventional activity' recited in the claims in that case because the steps 'add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.' *Id*. at 1299. While that conclusion might have been warranted in that case, given the fact that the 'conventional activities' in *Mayo* were the very steps that doctors were already doing—administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels—the Supreme Court did not limit its ruling to those particular facts and circumstances.

"The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally-inherited [cell-free fetal DNA] using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be 'routinely discarded,' '540 patent col.1 ll.50-53, because, as Dr. Evans testified, 'nobody thought that fetal cell-free DNA would be present.'

"It is hard to deny that [the] invention is truly meritorious. Prior to the '540 patent, prenatal diagnoses required invasive methods, which 'present[ed] a degree of risk to the mother and to the pregnancy.' *Id*. at col.1 ll. 16—17. The available 'techniques [we]re time-consuming or require[d] expensive equipment.' *Id*. at col.1 ll.17—37. Dr. Mark Evans testified that 'despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.' In a groundbreaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as 'a paradigm shift in non-invasive prenatal diagnosis,' and the inventors' article

describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests. Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in *Mayo* had been widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/inefficacy limits for years—here, the amplification and detection of [cell-free fetal DNA] had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. *Cf.* Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to 'a new way of using an existing drug' is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test).

"In short, [the] invention is nothing like the invention at issue in *Mayo*. [The patentees] 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859) (quoting *Household Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (same); *see generally* Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. (forthcoming 2015), *available at* http://ssrn.com/abstract=2398696 (last visited June 10, 2015) (analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

Ariosa, __ F.3d at __(Linn, J., concurring).

§15[a][1] Consideration of the Invention "as a Whole"

Stretching the *dicta* in *Mayo* to conclude that the invention in *Ariosa* lacks an "inventive" feature both fails to understand the limited holding of *Mayo* and that a stretched interpretation of *Mayo* runs smack into other lines of Supreme Court case law The *Adams Battery* case is instructive as to the "inventive" or nonobviousness nature of the invention in the *Ariosa* case.

As explained in *KSR:*

In *United States v. Adams*, 383 U.S. 39, 40 (1966), a companion case to *Graham* [*v. John Deere*, 383 U.S. 1 (1966)], the Court considered the obviousness of a 'wet battery' that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that *when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.* 383 U.S. at 50-51. It nevertheless rejected the Government's claim that Adams' battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52. *** The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams' design was not obvious to those skilled in the art."
KSR, __ U.S. at ___ (emphasis supplied).

It is impossible to read the specification of the patent in the *Ariosa* case and come to the conclusion that the invention lacks an "inventive" feature.
As explained in the *Adams Battery* case:

"While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, *Burns v. Meyer*, 100 U.S. 671, 672 (1880); *McCarty v. Lehigh Valley R. Co*., 160 U.S. 110, 116 (1895), it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention, *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946)."

Adams Battery case, *United States v. Adams*, 383 U.S. at 48-49.

The majority in *Ariosa* explains that "[i]t is undisputed that the existence of [cell-free fetal DNA] in maternal blood is a natural phenomenon. [The patentees have not] created or altered any of the genetic information encoded in the [cell-free fetal DNA], and it is undisputed that the location of the nucleic acids existed in nature before [the inventors] found them. The method ends with paternally inherited [cell-free fetal DNA], which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."

But, the starting material in the first step of the process in *Ariosa* was *not* "naturally occurring" but instead was *amplified* DNA. It is uncontested that, as explained by the majority, prior to the invention, maternal plasma and serum from maternal blood samples had previously been discarded as medical waste. The inventors discovered cell-free fetal DNA [ ] in such maternal plasma and serum in such blood samples previously thought of as mere waste.

It is manifest that the invention was a breakthrough. As pointed out in the separate opinion that distinguished itself from the majority:

"Prior to the [ ] patent, prenatal diagnoses required invasive methods, which 'present[ed] a degree of risk to the mother and to the pregnancy.' The available 'techniques [we]re time-consuming or require[d] expensive equipment.' [An

expert] testified that 'despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.' In [this] groundbreaking invention, [the inventors] discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as 'a paradigm shift in non-invasive prenatal diagnosis,' and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention … was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests. Unlike in *Mayo*, the [ ] patent claims a new method that should be patent eligible. *** The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. *Cf.* Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to 'a new way of using an existing drug' is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test)."

Dissecting the claim into its separate elements the majority "conclude[d] that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of [maternal DNA] into a patentable invention." The mistake made by the majority was to put together conventional steps to reconstruct the invention in hindsight when there was clearly no *motivation* to combine these steps.

The majority simply overlooks the fact that there is absolutely no *reason* in the prior art to combine the two steps, but in an obviousness determination it is necessary to provide such a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex*, 550 U.S. 398, 418 (2007). The majority overlooks the fact that the invention *as a whole* must be considered to determine whether there is an "inventive step" or – to use the wording of the statute – an

unobvious difference versus the prior art. The individual steps of the process in *Ariosa* were conventional, as were the steps in the Ochiai and Brouwer processes in *In re Ochiai,* 71 F.3d 1565 (Fed. Cir. 1995), and *In re Brouwer,* 77 F.3d 422 (Fed. Cir. 1996). In each case, each step of the claimed process was completely conventional.

Under the *Ochiai* and *Brouwer* cases it is manifest that there *is* an inventive concept in the invention of the *Ariosa* case that consists of the *combination* of otherwise conventional elements because of the breakthrough discovery to put the pieces of the combination together. The majority fails to give proper weight to the fact that there is absolutely no teaching in the prior art of step (a), the *amplification* of the DNA. There was clearly no *motivation* for a worker skilled in the art to amplify the DNA as nobody in the prior art appreciated that the otherwise insignificant of DNA in maternal fluid could be used for DNA testing. Thus, while it is obvious *how* to amplify DNA there was no *reason* to do so, absent the discovery by the patentees. Putting the puzzle pieces of the several elements together is only possible in hindsight without the inventive contribution made by the inventors as to how to put the puzzle together.

The failure to view the invention *as a whole* and the absence of *motivation* to combine otherwise conventional steps is explained in detail in the *Ochiai* case. The Board in *Ochiai* denied patentability because each of the steps of the claimed invention were conventional:

"The [prior art] references *** abundantly demonstrate the routineness of the claimed process. Thus, the Court rejected the argument that a conventional manipulation or reaction was unobvious "notwithstanding the specific starting material or resulting product or both, is not to be found in the prior art".

Ochiai, 71 F.3d at 1568 (quoting the Board's affirmance). The Board reasoned that:

"We are not here concerned with the patentability of the starting materials, the final compounds or other processes of making the [cephem] compounds. We are concerned only with the claimed process and the patentability thereof. Cases such as *In re Larsen*, 292 F.2d 531 (CCPA 1961); *In re Albertson*, 332 F.2d 379 (CCPA 1964) and, particularly, *In re Durden*, [763 F.2d 1406 (Fed. Cir. 1985)], all of which were directed to processes of making chemical compounds, are controlling herein.... In each case, a material A, either known or novel, was subjected to a standard process of reacting with a standard reactant, B, in order to produce the result expected from the reaction of A with B. Indeed in Albertson as in the instant case, the only manipulative step of the process is that which is embodied in the word 'reacting.'"

Id. In reversing the Board, the court in *Ochiai* stated that:

"One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure in the '429 application. As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, 'one cannot choose from the unknown.'"

Ochiai, 71 F.3d at 1569-70 (quoting *In re Mancy*, 499 F.2d 1289, 1293 (CCPA 1974))(footnote omitted). The Board added its further analysis; as explained by the court:

"The Board noted that Ochiai's specifically claimed acid is 'similar' to the acids used in the prior art. Likewise, the examiner asserted that the claimed acid was 'slightly different' from those taught in the cited references. Neither characterization, however, can establish the obviousness of the use of a starting material that is new and nonobvious, both in general and in the claimed process. The mere chemical possibility that one of those prior art acids could be modified such that its use would lead to the particular cephem recited in [the claim] does not make the process recited in [the claim] obvious "unless the prior art suggested the desirability of [such a] modification." *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir.1984). As we noted above, the examiner discussed no references containing any suggestion or motivation either (a) to modify known acids to obtain the particular one recited in [the claim], or (b) to obtain the particular new and nonobvious cephem produced by the process of [the claim 6. In short, the prior art contains nothing at all to support the conclusion that the particular process recited in [the claim] is obvious."

Ochiai, 71 F.3d at 1570. *Ochiai* was followed in a similar situation in *Brouwer*:

"The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.' 35 U.S.C. § 103. The inquiry is thus highly fact-specific by design. This is so 'whether the invention be a process for making or a process of using, or some other process.' *In re Kuehl*, 475 F.2d 658, 665 (CCPA 1973). When the references … fail to establish a prima facie case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071 1074 (Fed.Cir.1988).

"Applying this statutory test to the art of record, we conclude that Brouwer's process invention was not prima facie obvious. Although the prior art references … teach a generic chemical reaction of a compound containing an active methylene group with an ester of vinylsulfonic acid, we have made clear that '[t]he mere fact that a device or process utilizes a known scientific principle does not alone make that device or process obvious.' *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 1053 (Fed.Cir.1988). See also *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 1462 (Fed.Cir.1984) (same). * * * Without first knowing Brouwer's claimed process steps or the composition resulting from those steps, there is simply no suggestion in the references cited by the examiner to practice the claimed process. It was therefore not prima facie obvious."

In re Brouwer, 77 F.3d at 425.

§ 15[a][2] Focus on what is Claimed

In claim 1 of the invention in the *Ariosa* case the patentee utilizes fluid from the mother of a fetus where DNA has been *amplified*, absent which the minute traces of fetal DNA in the mother could not be detected. There was no recognition in the prior art that there was fetal DNA in the mother's fluid that could be basis for genetic testing.

The invention in *Ariosa* thus deals with a method to determine whether a particular DNA *exists* in a blood sample where there was no reason that a worker skilled in the art would think that such DNA would or could be present in the blood sample.

The invention in the *Ariosa* case has nothing to do with creating a derivative of a natural product based upon that natural product, but rather is simply a method to test whether the natural product, itself, is *present* in a particular sample where there was no reason to believe that such DNA could be present in the sample. The *Ariosa* case thus has nothing to do, for example, with the creation of a product derived from nature, but rather provides a test to see whether a natural product is present in a sample where there was no reason to believe it could exist. The case thus has nothing to do with the principles of the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.,* 133 S. Ct. 2107 (2013); nor *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012).

The invention in *Ariosa* thus not involve the situation of recognizing the natural properties of DNA, but instead involved the situation where a worker skilled in the art did not know the *existence* of a particular DNA in a fluid sample.

There was thus no *motivation* for a worker skilled in the art to substitute amplified DNA in the process of the *Ariosa* litigation.

"Motivation" to lead a worker skilled in the art to combine several elements together must be present to establish obviousness, whether that motivation is implicit or explicit. *"*One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a *known problem* for which there was an obvious solution encompassed by the patent's claims.") *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007)(emphasis added).

There was no "known problem" to provide where motivation to amplify the DNA for inclusion in the patented process. *Recognition* of a problem is one way to establish motivation, as explained in *Cross Medical Products, Inc. v. Medtronic Sofamor Danek*, 424 F.3d 1293 (Fed. Cir., 2005)(Linn, J.). Thus:

Evidence of a motivation to combine references need not be in the form of prior art. *See* [*Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1338-39 (Fed.Cir.2004)]. Evidence that a person of ordinary skill in the art recognized the same problem to be solved as the inventor and suggested a solution is, at the least, probative of a person of ordinary skill in the art's willingness to search the prior art in the same field for a suggestion on how to solve that problem. See *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed.Cir.1996) (Motivation to combine "may also come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." (citing *In re Rinehart*, 531 F.2d 1048, 1054 (CCPA1976))); *In re Huang*, 100 F.3d 135, 139 n. 5 (Fed.Cir.1996) (stating that problem well-known to a person of ordinary skill in the art would have directed that person of ordinary skill to the reference teaching the missing elements); see also, e.g., *In re Gartside*, 203 F.3d 1305, 1320-21 (Fed.Cir.2000) (recognizing that motivation to combine can come from the nature of the problem to be solved*); In re Rouffet*, 149 F.3d 1350, 1355 (Fed.Cir.1998) (same).

Cross Medical Products, 424 F.3d at 1323. The *Kaslow* case has a similar discussion:

"[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103."

In re Kaslow, 707 F.2d 1366, 1373 (Fed. Cir. 1983)(quoting *In re Sponnoble*, 405 F.2d 578, 585 (CCPA 1969); *see also In re Zurko*, 111 F.3d 887, 890 (Fed. Cir. 1997), *rev'd on other grounds*, 527 U.S. 150 (1999)(quoting *Sponnoble*, 405 F.2d at 578).

§ 15[a][3] *Ariosa* is Keyed to Extreme *Dicta* from *Mayo*

Both Professor Jeffrey Lefstin and Dr. Kevin Noonan have criticized the *Ariosa* majority opinion.

That the result in *Ariosa* was not compelled by the *holding* in *Mayo* is explained in detail by the noted scholar, Professor Lefstin:

"In *Ariosa*, the Federal Circuit has endorsed a highly restrictive interpretation of the test for patent-eligibility, one that was not mandated by *Mayo* itself. A test for 'inventive' application was only one of several possible analytical approaches set forth in *Mayo*. *Mayo* also suggested a test of non-generic application for patent-eligibility: that a claim must do more than state a law of nature or abstract idea, and append an instruction to 'apply it.' That was the aspect of *Mayo* stressed by *Alice*, which emphasized generic application far more than inventive application.

"As I argued in a recent paper, [Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 North Carolina Journal of Law and Technology 647 (2015),] under a test of generic application, the claims in *Ariosa* might fare differently than the claims in *Mayo*. The claims in *Mayo* represented generic applications, because they did no more than reveal the

results of the underlying relationship between 6-thioguanine levels and therapeutic efficacy. Arguably, at least some of the *Ariosa* claims do more than that: rather than claiming the natural phenomenon ([cell-free fetal DNA] in the maternal circulation) itself, they employ the natural phenomenon as a means to a achieve a different end (diagnosing a genetic condition of the fetus)."

"Moreover, the *Ariosa* opinion appears to endorse dissection of the claim to a degree not only contrary to *Diehr*, but beyond that suggested by *Flook* itself. While *Flook* explained that "the process itself" must be new and useful, *Ariosa* suggests that the individual steps of the process must be new and useful, and identifies the discovery of [cell-free fetal DNA] as "[t]he only subject matter new and useful as of the date of the application." Given that most inventions consist of rearrangements of old elements, it is difficult to understand how the court can refrain from addressing the claim steps as an ordered whole, as mandated by *Mayo* itself.

"And that highlights what is perhaps the most puzzling (or disturbing) aspect of *Ariosa*. According to Judge Linn's concurrence, the steps of the method *were* new: at the time of the invention, no one was amplifying paternally-inherited sequences from maternal serum or plasma, because no one thought that those fractions contained significant amounts of fetal DNA. That contrasts with *Mayo*, where the acts recited in the method were identical to those performed in the prior art. Yet Judge Linn believed that the Supreme Court's "blanket dismissal of conventional post-solution steps" in *Mayo* left no room to distinguish the *Ariosa* claims on those grounds.

"If the step of amplifying paternally inherited DNA from serum or plasma was new, by what analysis could the court could regard it as 'well-understood, routine, and conventional activity'? One way would be to sub-dissect that step into the conventional step of obtaining a cell-free fraction, and the conventional step of amplifying a sample containing DNA. That approach seems to lead to the *reductio ad absurdum* that most biotechnology processes are patent-ineligible, because they consist of the conventional steps of transferring drops of fluid from one tube to another.

"The alternative way would be to ask if the step of amplifying paternally inherited DNA would be obvious once it was known that there was [cell-free fetal DNA] in the maternal bloodstream. In other works, assume the patentee's discovery to be already known, and ask if the invention is obvious once the discovery is assumed

away. If that is truly the interpretation of *Mayo* signaled by *Ariosa*, then the case promises to cast a long shadow on the patent-eligibility of inventions based on discovery in the future."

Jeffrey A. Lefstin, *Ariosa v. Sequenom and the Path Ahead for Subject-Matter Eligibility*, Patently O Blog (June 14, 2015).

Even before the decision was reached in *Ariosa*, Professor Dennis Crouch foresaw the problems that the panel faced. *See* Professor Dennis Crouch, *Sequenom v. Ariosa: Invalidating the patent on Non-Invasive Pre-Natal Genetic Testing*, Patently O Blog (September 9, 2014)(discussing the then-pending appeal at the Federal Circuit). Following the decision, Dr. Kevin Noonan provided a sharply focused critique of the majority view in *Ariosa:*

[T]he Court appreciated that the inventors had found cell-free fetal DNA [ ] in maternal plasma or serum "*that other researchers had previously discarded as medical waste*" (emphasis added [by Dr. Noonan]). Foreshadowing their reasoning, the panel then state that "[a]pplying a combination of known laboratory techniques to their discovery, Drs. Lo and Wainscoat implemented a method for detecting the small fraction of paternally inherited [cell-free fetal DNA] in maternal plasma or serum to determine fetal characteristics, such as gender" (by which the opinion avoids the more significant uses such as detecting Downs syndrome and other fetal genetic defects). And more foreshadowing occurs when they characterize the development of this test as being a "discovery."

The opinion then acknowledges through the parties that the claims are not directed to [cell-free fetal DNA] *per se* or paternally inherited species thereof. In language that parallels Justice Thomas's language in Section III of his *Myriad* opinion, the opinion states that the '540 patent claims methods of using [cell-free fetal DNA] and then sets forth the panel's understanding of the technical basis for the claimed methods and the procedural particulars of the case below.

The panel's analysis is best understood using the Court's own language, to better appreciate the basis for this decision:

"In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent-ineligible concept. *Id.* at 1297. If the answer is yes, then we next consider the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. *Id.* at 1298. The Supreme Court has described the second step of this analysis as a search for an 'inventive concept' – i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.' *Id.* at 1294; *see also Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) ('Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible.').

Applying this understanding of the Supreme Court's teachings regarding diagnostic claims, the opinion states:

"It is undisputed that the existence of [cell-free fetal DNA] in maternal blood is a natural phenomenon. [The patentee] does not contend that [the inventors] Drs. Lo and Wainscoat created or altered any of the genetic information encoded in the [cell-free fetal DNA], and it is undisputed that the location of the nucleic acids existed in nature before Drs. Lo and Wainscoat found them. The method ends with paternally inherited [cell-free fetal DNA], which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring."

Of course, what the claimed methods end with are *amplified* [cell-free fetal DNA] *and* the diagnostic information that is discerned (but not claimed) using the method.

The opinion then takes isolated statements from the specification to support this conclusion (again, stating that [cell-free fetal DNA] was "routinely" discarded) and that the inventors surprisingly found that detecting [cell-free fetal DNA] could be used to render clinical diagnoses of fetal abnormalities non-invasively.

Of course, it is but a short analytical leap to find that the detection methods were simply "routine, conventional and well-understood" because the panel does not consider the claim as a whole but has broken its analysis into pieces (contrary to Supreme Court's *Diamond v. Diehr* decision). Accordingly, the panel determines that there is no "inventive concept" in the claims (bizarrely, relying as did the District Court on *Parker v. Flook*). (The applicability of that decision on life science inventions should have been firmly put to bed in Judge Rich's *In re Bergy* decision.) The next portion of the opinion nicely sets out the logical and legal flaws in the panel's decision:

"Like the patentee in *Mayo*, [the patentee here] contends that the claimed methods are patent eligible applications of a natural phenomenon, specifically a method for detecting paternally inherited [cell-free fetal DNA]. Using methods like PCR to amplify and detect [cell-free fetal DNA] was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect [cell-free fetal DNA]. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited [cell-free fetal DNA] is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of [cell-free fetal DNA] in maternal plasma or serum."

Unlike the patentee in *Mayo*, the inventors of the claimed invention here did something not done before their invention (detecting [cell-free fetal DNA] in maternal blood). In contrast, *every* step in the methods claimed in *Mayo* had been performed in the prior art; the only inventive aspect in those claims was the therapeutic ratio, which the Court found to be a 'natural law.' Accordingly, the *Mayo* claims did nothing more than recite the natural law. That is not the case here. Tragically, the remainder of this portion of the opinion recites the tedious evidence from the specification regarding known amplification and detection methods while ignoring that these methods had never been used to detect [cell-free fetal DNA] in maternal blood."

The opinion then visits preemption (sadly, the Circuit Court responsible for interpreting patent law does not correctly state the standard, *i.e.*, *undue* preemption; after all, *all* claims are preemptive in nature). Fortunately, the panel does not follow the District Court through the looking glass of requiring for patent eligibility that every newly claimed method to recite not only a new method but that there be commercially viable, non-infringing alternatives available at the time

an application is filed. Instead, the Court considers the preemption question moot once claims have been determined to be patent ineligible.

Finally, the Court insulates itself from the negative consequences its decision has on innovation by citing language (dicta) in *Myriad* that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry," illustrated by the interpretation that "[t]he discovery of the BRCA1 and BRCA2 genes was a significant contribution to the medical field, but it was not patentable" (ignoring the fact acknowledged twelve pages prior in the opinion that the inventors were *not* claiming [cell-free fetal DNA]).

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Judge Linn [in his concurrence] hoists the panel's decision on the petard of superior Supreme Court precedent:

"In short, [the patentee]'s invention is nothing like the invention at issue in *Mayo*. [Patentee] "effectuate[d] a practical result and benefit not previously attained," so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135–36 (1859) (quoting *Household Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (same); *see generally* Jeffrey A. Lefstin, *Inventive Application: a History*, [67 Fla. L. Rev. 565 (2015)] (analyzing traditional notions of patent eligibility of newly discovered laws of nature)."

* * *

It is clear that the Federal Circuit (or at least the members of this panel) believe that they are operating under a mandate from the Supreme Court regarding patent eligibility. On the contrary, the Court itself has on many occasions made it clear that they view their role (in patent law and otherwise) as setting forth the broad contours of the law that they expect the inferior courts to use to develop the law properly. In view of the lack of clarity in the *Mayo* opinion, a third year law student could distinguish this case from that one in arriving at the correct conclusion of patent eligibility. Nothing more than Supreme Court precedent itself (specifically, the *Diamond v. Diehr* decision which the Court did not overturn in *Mayo*) is needed for the task. The issue is not a lack of analytical and doctrinal tools but the will to employ them, which these members of the Federal Circuit do not seem to have had in rendering this decision. But shielding the Court from the consequences of their bad decisions does them a disservice. If the Court intended

to exclude from patent eligibility *all* genetic (nay all *types* of) diagnostic methods, the Federal Circuit owes it to the Court to give them the opportunity to say so clearly and reap the political consequences. * * *

Kevin E. Noonan, *Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015),* Patent Docs blog (June 22, 2015).

§ 15[a][4] The *Ariosa* Invention does not "Preempt" Research

The invention in *Ariosa* had absolutely nothing to do with the discovery of a product of nature. *Ariosa* thus has nothing to do with "preemption" of the DNA involved in the *Ariosa* claimed invention. Rather, the invention in *Ariosa* involved a new method to *identify* the presence of certain DNA. By analogy, consider the situation where a natural product cannot be identified by the human eye, without more, but *can* be identified through use of a "microscope". Imagine further that an inventor has discovered a new "microscope" that makes it easier and more accurate to identify the particular natural product. It is perfectly logical that one could claim either that "microscope" or a method of testing for the presence of the natural product by use of that "microscope", and that – assuming nonobviousness of the "microscope" – one should obtain a patent on the "microscope" or the method of use of the "microscope" to identify the natural product.

This is in essence the situation of the *Ariosa* case where the invention involves a new method for detecting the presence of DNA in a fluid sample but makes no claim to the DNA itself: There is no "preemption". Thus, a cornerstone argument in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289

(2012), against patent-eligibility of inventions involving "natural" subject matter is that granting patents on a derivative or use of the "natural" subject matter "preempts" research on a phenomenon of nature. Thus, it is stated that "[*Benson*] warn[s] us against upholding patents that claim processes that *too broadly preempt* the use of a natural law." *Mayo*, 132 S.Ct. at 1294 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)). An argument that the *dicta* in *Mayo* leads to the conclusion that the invention in *Ariosa* "preempts" research demonstrates the breadth of the *dicta* and leads to a result that has absolutely no impact whatsoever on the preemption of research on or use of the natural principle of the invention in *Ariosa*: The invention in *Ariosa* is a method to test for the existence of DNA in a blood sample and has nothing to do with patenting or using that DNA or a derivative of that DNA. There is simply no preemption even for commercial use of that DNA.

§ 15[a][5] Patents Do Not "Preempt" Research

Even if the use of the natural DNA in the *Ariosa* case were within the scope of claims of the patent in that case, this leaves the more fundamental question: Can the use of an invention to *experiment on* that invention *ever* be an act of infringement to see, for example, how the invention operates or to compare it to the prior art or to otherwise conduct research on the invention to make further improvements or design around the invention?

Until the Federal Circuit came into existence the answer was a clear "no". Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 Fed. Cir. B.J. 1 (2005)(herein: "Post-Merck Paper").

The Federal Circuit must accept a share of the responsibility for the failure of the patent community to understand the fundamental right to experiment "on" a patented invention. Despite a deep split within the Federal Circuit on this issue the appellate court has never seen fit to consider the issue *en banc.*

The starting point to understand the Federal Circuit split viewpoint is the state of the law leading up to *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193 (2005), as reported in the Post-Merck Paper. The dominant view of the former, recently retired Chief Judge is seen from *Integra Lifesciences I, Ltd. v. Merck KgaA*, 331 F.3d 860 (Fed. Cir. 2003)(Rader, J.) *rev'd*, *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193 (2005). The case involved a classic fact pattern of an experimentation "on" a patented invention. Yet, the dominance at the time of the view of the former Chief Judge was manifested by the accused infringer *refraining* from even raising this issue before the Federal Circuit. As explained in the majority opinion by the former Chief Judge, "Judge Newman's dissent [in this case does not] note that the judge-made [experimental use] doctrine is rooted in the notions of de minimis infringement better addressed by limited damages." *Integra Lifesciences I,* 331 F.3d at 863 n.2.

One panel leading up to the *Mayo* case uncritically accepted the view that "the[ ] exceptions [to statutory patent-eligibility under 35 USC § 101] have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years[.]'" *Prometheus Laboratories, Inc. v. Mayo Collaborative Serv.,* 628 F.3d 1347, 1353 (Fed. Cir. 2010)(Lourie, J.)(citing *Le Roy v. Tatham*, 55 U.S. (14 How.) at 174-75), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012). The holding in *Le Roy*

v. Tatham had absolutely nothing to do with patent-eligibility but rather dealt with the claiming of technology involving a lead pipe! A lead pipe!

While there have been recent opinions where some panels seem to understand that there *is* a right to experiment "on" a patented invention, the other side of the coin is that some panels continue to take the *Deuterium* route. *See, e.g., Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1356 (Fed. Cir., 2013)(Dyk, J.)(quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352–53 (Fed.Cir.2000) (Rader, J., concurring) ("[T]his court has not tolerated the notion that a little infringement—de minimis infringement—is acceptable infringement or not infringement at all.").

§ 15[b] Disclosure "Today" as Basis for Claims "Tomorrow"

Generic claim 1 in any application should, as a general rule, recite the "minimum elements" necessary to establish nonobviousness of an invention. In the case of a claim on the borderline of Supreme Court patent-eligibility standards, it is important to include at least one physical limitation as a prominent feature of the claims, and to include as many physical elements as possible *which are necessary for the commercial application of the invention.*

Perhaps more importantly, a "Diehr claim" should be presented that is modeled after the claims in *Diehr* which are cast as a method for curing rubber. This is in contrast to the "apply it" claims which downplay the physical element and have earned the scorn of the Supreme Court

The simple claim that recites an algorithm and essentially nothing more than a general instruction to "apply [the algorithm]" ("apply it") is easy to write but clearly a prescription for denial of patent-eligibility: *Alice Corporation Pty. Ltd. v. CLS Bank International,* 134 S. Ct. 2347, __ (2014), quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012)("*Mayo* made clear that transformation [of an abstract idea] into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' ")

Denial of "apply it" claims has been endorsed by the Federal Circuit. "[The court] must examine the limitations of the claims to determine whether the claims contain an 'inventive concept' to 'transform' the claimed abstract idea into patent-eligible subject matter. The transformation of an abstract idea into patent-eligible subject matter 'requires 'more than simply stat[ing] the [abstract idea] while adding

the words 'apply it.'"" *Ultramercial, Inc. v. Hulu, LLC*, __ F.3d __, __ (Fed. Cir. 2014)(Lourie, J.)(citations omitted)). As stated by one of the newer members of the court, "*Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., __ F.3d __, __ (Fed. Cir. 2015)(Reyna, J.)(quoting *Mayo*, 132 S. Ct. at 1294), quoting *Mayo*, 132 S. Ct. at 1294)).

A claim to a combination that includes a "conventional" element is novel and should be nonobvious where there is no reason in the prior art to combine that "conventional" element with the other element (or elements) of a combination claim. This should also be true if the only other element of the claim is itself unpatentable by virtue of being abstract or a product of nature and hence, as such element, lacking patent-eligibility under 35 USC §101 as in *Parker v. Flook*, 437 U.S. 584 (1978).

Under traditional patent principles, there is *novelty* in the combination of elements in each of these situations. In the area where the other component is abstract or a product of nature as in *Flook*, the real question under historic patent law principles is whether the combination is *obvious* under 35 USC § 103.

Flook is foundational case law for more recent Supreme Court decisions relating to patent-eligibility under 35 USC § 101, including *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), the *Myriad* case, *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014). A more

balanced view of the role of a "conventional" element is found in *Bilski v. Kappos*, 561 U.S. 593 (2010):

"Flook rejected '[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.' *Id*., at 590. The Court concluded that the process at issue there was 'unpatentable under §101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.' *Id*., at 594. As the Court later explained, *Flook* stands for the proposition that the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.' [*Diamond* v. *Diehr*, 450 U.S. 175, 191-92 (1981)].

"Finally, in *Diehr*, the Court established a limitation on the principles articulated in *Benson* and *Flook*. The application in *Diehr* claimed a previously unknown method for 'molding raw, uncured synthetic rubber into cured precision products,' using a mathematical formula to complete some of its several steps by way of a computer. 450 U. S., at 177. *Diehr* explained that while an abstract idea, law of nature, or mathematical formula could not be patented, 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.' *Id*., at 187. *Diehr* emphasized the need to consider the invention as a whole, rather than 'dissect[ing] the claims into old and new elements and then . . . ignor[ing] the presence of the old elements in the analysis.' *Id*., at 188. Finally, the Court concluded that because the claim was not 'an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products,' it fell within §101's patentable subject matter. *Id*., at 192."

To be sure, attempts have been made to minimize the impact of *Diehr* as seen from the *dictum* from Circuit Judge Plager in *Versata Software, Inc. v. SAP America, Inc.*,__ F.3d __, __ (Fed. Cir. 2015)(Plager, J.). In *Versata*, a panel minimized the precedential importance of *Diamond v. Diehr* on the basis that the claim was couched in terms of an industrial process – a method of curing rubber:

In *Alice* [*Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014)], the Court held that claims directed to the abstract idea of intermediated settlement were unpatentable, even though some of the claims required generic computer implementation. In *Bilski* [v. *Kappos*, 561 U.S. 593 (2010)], the Court held that claims directed to the abstract idea of risk hedging were unpatentable. In *Parker v. Flook*, 437 U.S. 584 (1978), the Court held that a mathematical formula for computer alarm limits in a catalytic conversion process was a patent-ineligible abstract idea. In *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Court held that claims involving an algorithm for converting binary-coded decimal numerals into pure binary form were unpatentable since the patent was, in practical effect, a patent on the algorithm itself.

These cases may be contrasted with *Diamond v. Diehr*, 450 U.S. 175 (1981), in which the Court held that a computer-implemented process for curing rubber was patent eligible even though it employed a well-known mathematical equation. It used the equation in a process to solve a technological problem in conventional industry practice."

§ 15[b][1] Combination Definition Integrating an Inventive Feature

A common undercurrent in the patent-eligibility cases particularly since *Bilski* v. *Kappos*, 561 U.S. 593 (2010), has been the concern that a patent on an abstract idea or principle would "preempt" future research. *Alice* is just a more recent iteration of the Supreme Court concern for preemption: "We have described the concern [over § 101] that drives this exclusionary principle as one of pre-emption." *Alice*, 134 S. Ct. at 2354 (quoting *Bilski* v. *Kappos*, 561 U.S. 593, 611-12 (2010)). The concern is the impact of "upholding the patent 'would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea'" *Id.*

Stating that "[l]aws of nature, natural phenomena, and abstract ideas are 'the basic tools of scientific and technological work[,]'" *Alice*, 134 S. Ct. at 2354 (quoting *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)), the Court states that "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,' thereby thwarting the primary object of the patent laws." *Alice*, 134 S. Ct. at 2354 (quoting *Mayo* and the U.S. Const., Art. I, § 8, cl. 8, that "Congress 'shall have Power . . . To promote the Progress of Science and useful Arts'").

The Court reiterates the position with reference to a mid-nineteenth century case: "We have 'repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity.'" *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, citing *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 113 (1854)).

§ 15[b][2] Pinpointing the Inventive Feature in a Combination Claim

In *Alice* the Court also recognizes that it must draw the line to *permit* patenting of inventions because a naked "preemption" argument would foreclose patentability in many areas of technology. Thus, after stating its preemption theory to block patenting of abstract ideas, the Court adds an important caveat:

"At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo*, [supra]. At some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.' Id., …). Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond* v. *Diehr*, 450 U.S. 175, 187 (1981). '[A]pplication[s]' of such concepts ''to a new and useful end,'' we have said, remain eligible for patent protection. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

"Accordingly, in applying the §101 exception, we must distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more, *Mayo*, [supra], thereby 'transform[ing]' them into a patent-eligible invention, *id.*,…. The former 'would risk disproportionately tying up the use of the underlying' ideas, *id.*,…., and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws."

Alice, 134 S. Ct. at 2354-55.

Nothing in *Alice* in any way suggests that subject matter should be preempted that is both novel and nonobvious, i.e., "inventive". Indeed, the same concerns that motivated the Supreme Court to judicially legislate a standard of "invention" are identically applicable to the concerns expressed by the Supreme Court under the theory of "preemption" in *Alice* and the other patent-eligibility cases.

Instead of dealing with an issue of patent-eligibility, the Court in *KSR* invalidated the "gas pedal" patent on the basis that "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . .

useful Arts.' This is the *standard* expressed in the Constitution and it may not be ignored." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 427 (2007)(citing U.S. Const., Art. I, § 8, cl. 8). Thus, "[t]hese premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* [v. *Greenwood*, 52 U.S. (11 How.) 248 (1851),] and codified in § 103." *Id.*

The same theme was stated in *Anderson's-Black Rock: "*Congress may not authorize the issuance of patents whose effects are to *remove existent knowledge from the public domain, or to restrict free access to materials already available." Anderson's-Black Rock, Inc. v. Pavement Salvage Co*., 396 U.S. 57, 61 (1969)(emphasis added).

While the Court in *Alice* seeks to draw a line between what is and what is not patent-eligible based upon preemption, the way the line is drawn is based upon whether the claimed subject matter is "inventive". But, this is synonymous with whether subject matter is non-obvious. The identical preemption concerns apply for both the "abstract" ideas and the clearly conventional technology of the section 103 cases: In both settings, the patent should not preempt known or obvious basic building blocks for future innovation.

If the Supreme Court can be faulted for perpetuating the false idea that patents *preempt* research, the blame must also be shared by the Federal Circuit that has long had an element that shared this viewpoint. A central point of the *Myriad* petition is the notion that any patent *preempts* follow-on research, a problematic premise in the context of two centuries of contrary domestic precedent that has been a model for the major patent regimes around the world.

§ 15[b][3] "Conventional" Element vs. Combination "As a Whole"

One may agree, *arguendo,* that the methodology in *Flook* was wrong and in violation of the "all elements" rule. But, at first blush, the question may be asked: Why does it matter that a "conventional" element of the claim is disregarded in the evaluation of a combination claim?

The principal reason *why* a claim is drafted with plural elements is precisely because it is the *combination* that is evaluated, *as a whole,* in determination of patentability. Thus, if there are elements "A" and "B" in a patented combination and "A", standing alone, is patentable, while "B", standing alone, is conventional, the manifest approach to obtaining maximum breadth would be *not* to claim the combination A+B but claim the element A-alone, because the claim to the element A-alone covers that element, by itself, as well as *any* combination with any manner of other element(s). The only reason *why* the "conventional" element "B" is included in "claim 1" is because element "A" may not be *per se* patentable, but the *combination* may be unexpected (and hence patentable).

The error in *Flook* may be seen from the explanation in *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955 (Fed. Cir. 1986)(E. Smith, J.):

> "The dispositive question is not whether the claimed device is an 'invention'; rather, it is whether the invention satisfies the standards of patentability. 35 U.S.C. §§ 100-103. To suggest that [the patentee]'s new combination 'is not necessarily an invention' or otherwise to require some concept of 'inventiveness' or 'flash of genius' for patentability would improperly misplace the focus of 35 U.S.C. Sec. 103.

"That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole. 'There is no basis in the law * * * for treating combinations of old elements differently in determining patentability.' As stated in *Stratoflex*:

"The reference to a 'combination patent' is equally without support in the statute. There is no warrant for judicial classification of patents, whether into 'combination' patents and some other unnamed and undefined class or otherwise. Nor is there warrant for differing treatment or consideration of patents based on a judicially devised label. Reference to 'combination' patents is, moreover, meaningless. Virtually all patents are 'combination patents,' if by that label one intends to describe patents having claims to inventions formed of a combination of elements. It is difficult to visualize, at least in the mechanical-structural arts, a 'non-combination' invention, i.e., an invention consisting of a single element. * * *" [*Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed.Cir.1983)(original emphasis).]

"Casting an invention as 'a combination of old elements' leads improperly to an analysis of the claimed invention by the parts, not by the whole. That is what seems to have happened here. The critical inquiry is whether ' 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' [*Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed.Cir.1985) (emphasis in original), quoting *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co*., 730 F.2d 1452, 1462 (Fed. Cir. 1984).]"

Custom Accessories, 807 F.2d at 959 (footnotes integrated into text in brackets or deleted).

§ 15[b][4] *Diehr* vs. a Simplistic "Apply it" Claim Approach

The simple claim that recites an algorithm and essentially nothing more than a general instruction to "apply [the algorithm]" ("apply it") is easy to write but clearly a prescription for denial of patent-eligibility: "*Mayo* made clear that transformation [of an abstract idea] into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' " *Alice Corporation Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347, __ (2014)(quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1294 (2012)).

The Federal Circuit has underscored its view that an "apply it" application of an algorithm lacks patent-eligibility: "[The court] must examine the limitations of the claims to determine whether the claims contain an 'inventive concept' to 'transform' the claimed abstract idea into patent-eligible subject matter. *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1294, 1298). The transformation of an abstract idea into patent-eligible subject matter 'requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'' *Id.* (quoting *Mayo*, 132 S. Ct. at 1294)." *Ultramercial, Inc. v. Hulu, LLC*, __ F.3d __, __ (Fed. Cir. 2014)(Lourie, J.); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(Reyna, J.)(quoting *Mayo*, 132 S. Ct. at 1294)("*Mayo* made clear that transformation into a patent-eligible application requires 'more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' "). *See also* § 15[a][7], *Adams and Ochiai Consideration of the Invention "as a Whole"* (discussing the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39 (1966), and *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995)).

The better approach is to provide a claim to an overall process where the algorithm is just one of the elements of the claim as exemplified by the claim in *Diamond v. Diehr*, 450 U.S. 175 (1981), to a method of curing rubber.

§ 15[c] Mythology of *"[S]tare decisis going back 150 years"*

"Although not compelled by the statutory text, the Court has held that "the[ ] exceptions [to statutory patent-eligibility] have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years[.]'" *Prometheus Laboratories, Inc. v. Mayo Collaborative Serv.*, 628 F.3d 1347, 1353 (Fed. Cir. 2010)(Lourie, J.)(citing *Le Roy v. Tatham*, 55 U.S. (14 How.) at 174-75), *subsequent proceedings sub nom Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

To be sure, the Supreme Court itself has characterized the case in similar terms. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)(citing *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1853))(" "[P]atents cannot issue for the discovery of the phenomena of nature."); *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347, 2354 (2014)(quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013))("[The Supreme Court has] interpreted § 101 and its predecessors ... for more than 150 years [to] contain[ ] an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.' ")

Beyond *Prometheus*, other Federal Circuit cases discussing *Le Roy v. Tatham* include *In re Bilski*, 545 F.3d 943, 952 (Fed. Cir. 2008)(Michel, C.J.)(quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852)("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); *Classen Immunotherapies Inc. v. Idec*, 659 F.3d 1057, 1080 (Fed. Cir. 2011)(Moore, J., dissenting) (quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 173 (1853) ("A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.").

§ 15[c][1] *Household Coal* Nineteenth Century English Precedent

Household Coal & Iron Co. v. Neilson, Webster's Patent Case 673, 683 (House of Lords 1843)), is cited as foundation for *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852). *See* Jeffrey A. Lefstin, *Inventive Application: a History*, 67 Fla. L. Rev. 565, 594-96 (2015)(analyzing traditional notions of patent eligibility of newly discovered laws of nature); cf. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __, __ (Fed. Cir. 2015)(Linn, J., concurring)("Sequenom's invention is nothing like the invention at issue in *Mayo* [*Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012)]. Sequenom 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859)(quoting *Household Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (same); see generally Jeffrey A. Lefstin,

Inventive Application: a History, 67 Fla. L. Rev. [565, 594-96 (2015)](analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.").

Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1852), states that:

"A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. *It is said, in the case of the Household Company v. Neilson, Webster's Patent Cases, 683, 'A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.'*"

Le Roy v. *Tatham*, 55 U.S. (14 How.) at 175 (emphasis added). The emphasized portion of this opinion is repeated in *Le Roy* v. *Tatham*, 63 U.S. (22 How.) 132 (1859). *See also In re Bergy*, 596 F.2d 952, 991 (CCPA 1979)(Baldwin, J., concurring)("A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process. This is required by the patent laws of England and of the United States, in order that when the patent shall run out, the public may know how to profit by the invention. It is said, in the case of the *Household Company v. Neilson*,

1 Webs. Pat. Cas., 683, 'A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.' *Id.* at 174-5.")

Household Coal, however, had absolutely nothing to do with patent-eligibility, as explained by Professor Lefstin, *supra.*

§ 15[c][2] *Le Roy v. Tatham*, The Lead Pipe Case

Le Roy v. Tatham has nothing to do with an "abstract" idea.

The invention involved was to a method of making a lead pipe.

A lead pipe!

A detailed analysis of the case is provided by Professor Jeffrey A. Lefstin, *Inventive Application: A History*, 67 Fla. L. Rev. 565, 594-96 (2015). In contrast to the characterization of *Le Roy v. Tatham* since *Funk v. Kalo* nineteenth century case law more properly provides a more contemporaneous explanation of the case.

A Supreme Court case from the same century, *Busell Trimmer Co v. Stevens*, 137 U.S. 423 (1890)(Lamar, J.). *See also* Professor Jeffrey A. Lefstin, *Inventive Application: A History*, 67 Fla. L. Rev. 565, 594-96 (2015). As explained in *Bussell Trimer:*

In *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 177 (1853), … the claim was for a combination of old parts of machinery to make lead pipes, in a particular manner, under heat and pressure. The combination was held not to be patentable, the court saying: 'The patentees claimed the combination of the machinery as their invention in part, and no such claim can be sustained without establishing its novelty, not as to the parts of which it is composed, but as to the combination.' The court also quoted, with approval, the following from *Bean v. Smallwood*, 2 Fed. Cas. 1142 (No. 1,173)(D. Mass. 1843), an opinion by Mr. Justice STORY: 'He [the patentee] says that the same apparatus, stated in this last claim, has been long in use, and applied, if not to chairs, at least in other machines, to purposes of a similar nature. If this be so, then the invention is not new, but at most is an old invention or apparatus or machinery applied to a new purpose. Now, I take it to be clear that a machine or apparatus or other mechanical contrivance, in order to give the party a claim to a patent therefor, must in itself be substantially new. If it is old and well known, and applied only to a new purpose, that does not make it patentable.'"

Busell Trimmer, 137 U.S. at 433-34.

Bean v. Smallwood is just one of several leading cases standing for the proposition that the application of an old process to a new use lacks patentable novelty. See *Dunbar v. Myers*, 94 U.S. 187, 199 (1876)(Clifford, J.)(citing *Howe v. Abbott*, 12 Fed. Cas. 42 (No. 6,766)(D. Mass. 1842)(Story, J.); *Bean v. Smallwood*, 2 Fed. Cas. 1142 (No. 1,173)(D. Mass. 1843); *Glue Co. v. Upton*, 97 U.S. 3 (1877))("Judge Story held, many years ago, that the mere application of an old process, machine, or device to a new use was not patentable,— that there must be some new process or some new machinery to produce the result, in order that the supposed inventor may properly have a patent for the alleged improvement."). See also *Brown v. Piper*, 91 U.S. 37, 41 (1875)(Swayne, J.)(citing, *inter alia*, *Howe v. Abbott* and *Bean v. Smallwood*)("[T]his was simply the application by the patentee of an old process to a new subject, without any exercise of the inventive faculty, and without the development of any idea which can be deemed new or original in the sense of the patent law. The thing was within the circle of what was well known before, and belonged to the public. No one could lawfully appropriate it to

himself, and exclude others from using it in any usual way for any purpose to which it may be desired to apply it.").

As explained in *Diehr,* "[t]he question … of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" *Id., quoting Diamond v. Diehr,* 450 U.S. 175, 190 (1981), quoting *In re Bergy*, 596 F.2d 952, 961 (CCPA 1979)(Rich, J.).

To be sure, *Le Roy v. Tatham* is not the only case relied upon by the Court as basis for an exception to patent-eligibility. Other notable cases having nothing to do with patent-eligibility but instead deal with the nineteenth century invention of the eraser-tipped pencil, the *Rubber-Tip Pencil* case, *Rubber-Tip Pencil* ***Co. v.*** *Howard*, 87 U.S. (20 Wall.) 498 (1874), and the more modern aggregation of several known species of microorganism in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

The *Rubber-Tip Pencil* case has been cited for "the longstanding rule that 'an idea of itself is not patentable." *See Diamond v Diehr,* 450 U.S. at 164-65 (dictum)(citing *Rubber-Tip Pencil,* 87 U.S. (20 Wall.) at 507), and other cases for the proposition that "[t]his Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.'); *see also Parker v. Flook,* 437 U.S. at 598-99 (Stewart, J., joined by Burger, C.J., Rehnquist, J., dissenting)(citing *Rubber-Tip Pencil,* 87 U.S. (20 Wall.) at 507), and other cases for the proposition that '[i]t is a commonplace that laws of nature, physical phenomena, and abstract ideas are not patentable subject matter [under 35 USC § 101]. A patent could not issue, in other words, on the law of gravity, or the multiplication tables, or the phenomena of magnetism, or the fact that water at sea

level boils at 100 degrees centigrade and freezes at zero –even though newly discovered.'"

The first two paragraphs of the opinion in the *Rubber-Tip Pencil* case make it crystal clear that it was *acknowledged* that the claimed rubber-tipped pencil *is* an "article of manufacture" (and hence to patent-eligible subject matter). But, the question presented was whether this new article of manufacture is *patentable* in the sense of what today are the patentability considerations of novelty and nonobviousness:

"The question which naturally presents itself for consideration at the outset of this inquiry is, whether the new article of manufacture, claimed as an invention, was patentable as such. …

"A patent may be obtained for a new or useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof. In this case…, [the] patent was for 'a new manufacture,' being a new and useful rubber head for lead-pencils. It was not for the combination of the head with the pencil, but for a head to be attached to a pencil or something else of like character. It becomes necessary, therefore, to examine the description which the patentee has given of his new article of manufacture, and determine what it is, and whether it was properly the subject of a patent."

Rubber-Tip Pencil, 87 U.S. (20 Wall.) at 504-05.

Patentability was denied under classic principles of novelty and nonobviousness:

"But the cavity [of the claimed pencil] must be made smaller than the pencil and so constructed as to encompass its sides and be held thereon by the inherent elasticity of the rubber. This adds nothing to the patentable character of the invention. Everybody knew, when the patent was applied for, that if a solid substance was inserted into a cavity in a piece of rubber smaller than itself, the rubber would cling to it. The small opening in the piece of rubber not limited in form or shape, was not patentable, neither was the elasticity of the rubber. What, therefore, is left for this patentee but the idea that if a pencil is inserted into a cavity in a piece of rubber smaller than itself the rubber will attach itself to the pencil, and when so attached become convenient for use as an eraser?

"An idea of itself is not patentable, but a new device by which it may be made practically useful is. The idea of this patentee was a good one, but his device to give it effect, though useful, was not new."

Rubber-Tip Pencil, 87 U.S. (20 Wall.) at 507.

The holding in the *Rubber-Tipped Pencil* case was to the product still in use today, the modern pencil pointed at one end with "lead" and eraser-tipped at the other, which was found invalid over the prior art under what today would be obviousness under 35 USC § 103(a).

For one year short of a full quarter century, *Funk v. Kalo* was a relatively obscure case holding that an aggregation of bacterial was obvious or – to use the terminology before the 1952 Patent Act – lacked "patentable invention". Twenty-four years later the author of the *Benson* case latched onto *dicta* from his previous majority opinion in *Funk v. Kalo* as basis for sweeping statements denying patent-eligibility to software technology.

The Bond invention claimed in *Funk v. Kalo* is to a classic "manufacture" or "article of manufacture", a novel mixture of bacterial: "An inoculant … comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium…." *Funk v. Kalo*, 333 U.S. at 128 n.1 (quoting claim 4).

Indeed, the Court recognizes that Bond's mixture is a "new and different *composition*":

"The Circuit Court of Appeals [in its ruling sustaining patent validity] thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants."
Funk v. Kalo, 333 U.S. at 130-31.

The *holding* in *Funk v. Kalo* was that this combination lacked "invention" – the pre-1952 *Hotchkiss*-based wording of the day for the standard of what four years later under the 1952 Patent Act was codified as a standard of nonobviousness under what today is 35 USC § 103(a).

The *holding* in *Funk v. Kalo* focused upon invention in the sense of obviousness as stated by the Court itself: Bond's "*aggregation of species* fell short of invention within the meaning of the patent statutes." More completely stated:

"The Circuit Court of Appeals [in its ruling sustaining patent validity] thought that Bond did much more than discover a law of nature, since he made a new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that that *aggregation of species* fell short of invention within the meaning of the patent statutes."

Funk v. Kalo, 333 U.S. at 130-31 (emphasis added).

The focus on obviousness is underscored by the concurring opinion of Justice Frankfurter: "Insofar as the court below concluded that the packaging of a particular mixture of compatible strains is an invention [in the sense of patent-eligibility] and as such patentable, I agree, provided not only that a new and useful

property results from their combination, but also that *the particular strains are identifiable and adequately identified.*" *Funk v. Kalo,* 333 U.S. at 133 (Frankfurter, J., concurring)(emphasis added). He points out that the Bond claim failed to *identify* the particular strains which were basis for the claim of his unobvious result.

The majority attributes the beneficial results of the patentee's work to "nature": "Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their *qualities are the work of nature*. Those qualities are of course not patentable."

Manifesting his knowledge of science *vel non* Justice Douglas states:

"Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. …The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee."

Funk v. Kalo, 333 U.S. at 130.

The quoted statement of opinion relates not to the law but to the relation of science to a mystical belief of nature and has been outdistanced by the growth of scientific knowledge:

Particularly in earlier centuries and millennia but still well into the twentieth century, where there is no scientific explanation for a phenomenon, the explanation was often that this was a "nature's secret". As the frontiers of science rolled back the areas of uncertainties, what had been "nature's secret" was now attributable to a rational scientific explanation. One of the last bastions of a mystical belief in "nature's secrets" relates to the explanation of mechanisms of pharmaceutical and agricultural phenomena where there is no explanation available from science.

One may see the spread of science filling the void of knowledge in the field of cancer treatments. Whereas little more than a generation ago a diagnosis of cancer was usually a diagnosis of impending death, whereas today more and more cancers are treatable and in some areas the prognosis for recovery outweighs the alternative. Yet, specific cancer treatments remain elusive as only one out of literally thousands of compounds has true efficacy in humans and many cancers remain untreatable.

§ 16. Method of Making or Using a Product

§ 16[a] Method of use claims

Method of use claims are important for a novel and unobvious use of a known product. Such claims are also useful where the use is novel and unobvious even if the product is seemingly patentable.

If there is close prior art to a claimed compound *but for a different utility* then the method of use claim can remain valid even if the compound, per se, lacks novelty or is obvious.

§ 16[b] Method of making a Novel Product

Where a chemical or biotechnology new entity is patentable, the "analogy process" of making that product may also be patentable. Thus, consider the situation where there is a new molecule

$$AB_1$$

that is produced by the synthesis

$$A + B_1 \rightarrow AB_1$$

which follows the prior art method

$$A + B \rightarrow AB.$$

§ 16[b][1] Classic German "Analogie Verfahren" Claims

Historically, and since the very first Federal Patent Law of Germany in the nineteenth century, claims to the "Analogie Verfahren" (analogy process) were quasi-product claims used by the German chemical and pharmaceutical industries to protect their new products. A novel and nonobvious compound could not be claimed, *per se*, but the *method* for making that compound through obvious methods was patentable. Furthermore, if the product were novel, then a presumption arose that the sale of the same product was made by the accused infringer.

§ 16[b][2] *Ochiai* Establishment of Patentability

Historically, the German "analogy process" claim was not recognized as patentable under the notorious *Larsen* case:

More than fifty years ago in *Larsen* it was established that an "analogy process" for making a new chemical product through conventional synthesis is obvious, because "given" the identity of the final product, the selection of the reactants would be obvious. *In re Larsen*, 292 F.2d 531 (CCPA 1961)(Rich, J.); *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985). In reaffirming *Larsen* the court in *Durden* explained that:

"A process, after all, is a manipulation according to an algorithm, as we have learned in recent years – doing something to or with something according to a schema. The argument is that an otherwise old process with a predictable outcome is unobvious because it is applied to a new material, notwithstanding the new material is similar or analogous to materials identically manipulated or treated before. *To anyone other than a patent lawyer and therefore unfamiliar with the mysteries of patent claims, this would make little sense, we believe*. Appellants conclude their argument with the assertion that they 'are entitled to claim their invention as they see fit,' which is indisputable. 35 U.S.C. Sec. 112, second paragraph. But when it comes to determining whether their claim is allowable under Sec. 103, as was said in [*In re Albertson*, 332 F.2d 379 (CCPA 1964),] and elsewhere, we must treat the claim as we find it. We hold the process claim before us to be directed to obvious subject matter in view of [the prior art]. We do not find that *Albertson* has been previously overruled *sub silentio*, as the dissenters believe, and we do consider it a viable precedent which fully supports this decision."

Durden, 763 F.2d at 1410-11 (emphasis added).

Durden, if not overruled, was distinguished to pave the way for patenting an "analogy process", in *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995). As explained in *Ochiai:*

"The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.' 35 U.S.C. Sec. 103. The inquiry is thus highly fact-specific by design. This is so 'whether the invention be a process for making or a process of using, or some other proce ss.' [*In re Kuehl*, 475 F.2d 658, 665 (CCPA 1973)]. When the references cited by the examiner fail to establish a prima facie case of obviousness, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071 1074 (Fed.Cir.1988).

"Applying this statutory test to the art of record, we conclude that Ochiai's process invention as claimed is not prima facie obvious. The process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure in the '429 application. As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, 'one cannot choose from the unknown.' [*In re Mancy*, 499 F.2d 1289, 1293 (CCPA 1974)]."

§ 16[b][3] Backup Protection for Important Product Inventions

A claim to the method of making a new compound through a conventional chemical reaction provides backup protection for compound inventions. In some situations an at first blush novel compound is later discovered to have been produced as a byproduct or occurs as part of a natural extract. If claims to the product are invalidated, then the claim to the organic synthesis of the compound may well survive. For example, if it is later discovered that a product produced through an analogy process claim is anticipated due to the production of the product as a minor impurity in a different prior art process, the process claim may well survive a validity test.

§ 16[b][4] Meaningful Protection under the Process Patents Amendments Act

Method of making claims at one time had the serious drawback of limited applicability to products made offshore because there is no direct infringement of a process claim under 35 USC § 271(a) where a process is practiced overseas, and the product of that process is imported into the United States.

Congress plugged this loophole with the Process Patents Amendments Act of 1988. Thus, "[35 USC §] 154(a)(1) did not include the right to exclude others from using products made by a patented process—statutory provisions that were not implemented until 1988. Process Patents Amendment Act of 1988 [ ], P.L. 100–418, §§ 9002, 9003, 102 Stat. 1107, 1563–64 (1988)." *Zoltek Corp. v. United States*, 672 F.3d 1309, 1320 (Fed. Cir. 2012)(en banc)(Gajarsa, J.).

♦ ♦ ♦ ♦

§ 17 Product-by-Process Claims

Is a product-by-process claim infringed when the *same product* is produced by a different process than identified in the claim? Currently, the answer in the United States is "no" based upon the the *en banc* decision in *Abbott Laboratories v. Sandoz, Inc*., 566 F.3d 1282 (Fed. Cir. 2009)(en banc in relevant part)(Rader, J.).

But, the answer is "yes" in at least Japan, thanks to the recent Supreme Court decision in that country in *Pravastatin Sodium Case* (Japan Supreme Court, June 5, 2015, Second Petty Bench, case Nos. 2012(ju)1204 and 2012(ju) 2658); *see also* Dr. Shoichi Okuyama, *Pravastatin Sodium Case, Japan Product-by-Process Claiming Practice: Supreme Court Overrules the Grand Panel of the IP High Court* (June 8, 2015).

To be sure, it is *always* preferable to claim a new chemical or biotechnology entity where the entity is identified by the structural formula as the "label" for the product. The only exception is where there is any uncertainty as to whether a structural formula thought to represent such an entity may not in fact be correct. Where this is a close call, the structural formula claim should be presented as "claim 1" while an "insurance" claim in product-by-process format should be set forth in a separate claim.

Domestically, the law concerning product-by-process claiming appears, at the moment, to be stable. This is only after conclusion of a "Twenty Years War" between two of the key protagonists of the past generation that had quarreled over the scope of product-by-process protection is seemingly over in view of *Abbott v. Sandoz*, but, is the "war" *really* over?

Where science permits a clear structural formula definition of a new chemical entity, claims to the new entity are easy to draft by simple naming of the "label", the structural formula, that identifies the new entity such as by an international standard for of chemical nomenclature. But, where the patent applicant at the time of filing has not been able to successfully identify the "label", the structural formula, resort has historically been attempted to define the new entity in terms of the ingredients used to synthesize that new entity through a "product by process" claim.

Whether a claim to a product has a "label" to identify the product – its structural formula – or defines the product by its method of production – the product-by-process claim, it must be remembered that in both cases it is the *product* defined in either way that is important. Thus, whether the claim in question is defined as a "product", *per se*, or styled through a "product-by-process" definition, it is the *product* that is the invention; it is identical no matter whether it is identified by a structural formula as in a pure product claim or as a product-by-process.

Thus, in both cases, it is three dimensional "thing", the compound that is the invention; a structural formula is merely a "label", an *identifier* of the claimed compound: "[A] formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it." *Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, Inc.*, 630 F.2d 120, 128 (3rd Cir. 1980)(quoting *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)). See also *Commissioner of Patents v. Deutsche Gold-und-Silber-Scheideanstalt Vormals Roessler*, 397 F.2d 656, 662 (D.C. Cir., 1968)(same); *In re Herr*, 377 F.2d

610, 622 (C.C.P.A., 1967)(same); see also § 16[e][1], *Late Stage Conversion to True Product Protection.*

There has historically been a discrimination shown against the use of a product-by-process claim including a "rule of necessity": A product-by-process claim has historically been procedurally proscribed by the patent offices of the world unless it was *necessary* to use this claim format. There is good reason for the "rule of necessity" because the structural formula as a label for a new product is much easier for the public to understand to grasp the boundaries of the scope of protection of the patent claim.

While the United States has abandoned the rule of necessity for presentation of product-by-process claims, a different viewpoint is seen in both Europe and Japan as manifested by the Supreme Court of Japan that has departed from the United States to interpret a product-by-process claim as covering the same product made by a process not described in the product-by-process claim. *See* § 16[e][5][b], *Japan Adoption of the Rule of Necessity* (discussing the *Pravastatin Sodium Case*); *see also* Shoichi Okuyama, *supra*. Europe, too, has an independent voic. *See* § 16[e][5][b], *EPO Adoption of the Rule of Necessity* (discussing *Hospira UK Ltd. v. Genentech Inc.*, [2014] EWHC 3857 ¶ 147(iii), (Pat)(High Court 2014)(Birss, J.).

A major reason that the rule of necessity has been relaxed in the United States is because – apart from the "Twenty Year Patent War" within the Federal Circuit – the American rule for product-by-process claiming has been to limit the scope of protection of such a claim to the very product identified by the process features *but to exclude the identical product made by a different process.* This feature of the American rule serves the function of giving the public clear guidance

on the limited scope of protection of a product by process claim while also providing a powerful incentive to the patent applicant to claim a new entity in the classic structural formula claim. Whether the "Twenty Year War" is over or not remains to be seen. See *The Twenty Year War, Is it Over?*, in § 16[e][3][b], *Minority View that Product made by Any Process Infringes*.

Yet, another feature of the *Pravastatin Sodium Case* of the Japan Supreme Court is that this highest court in Japan has interpreted product-by-process claims to cover the same product identified by the process details, *but when made by any process.* Thus, the Japan Supreme Court adopted a holding consistent with the Newman dissent: Now, in Japan, a product-by-process claim provides coverage for the same product defined by that claim *when produced by any process. See* § 16[e][3][c], *Japan Adopts the Result of the Newman Dissent; see also* Shoichi Okuyama, *supra***.**

In the context of Japan's new liberality favoring the patentee as to scope of protection, the incentive to use structural formula claiming is greatly diminished. In that context, it is understandable why the Supreme Court reinstituted the rule of necessity.

Open questions still remain: For example, if the applicant has been forced to use product-by-process terminology because of a lack of understanding of the structural formula *at the time of filing*, what measures can the applicant take to *amend* the specification to identify the structural formula and change the format of his claims? Where it is not altogether certain whether the applicant correctly understands the composition, should the applicant be permitted to have *both* types of claims?

The *Ashless Dispersant* case provides a graphic example where a true product claim was presented which included an "ashless dispersant" but which during the litigation was discovered to disappear *in situ*. *Ashless Disperant* Case, *Exxon Chemical Patents, Inc. v. Lubrizol Corp*., 64 F.3d 1553 (Fed. Cir. 1995)(Clevenger, J.), discussed at § 16[e][2], *Ashless Dispersant Case, Product-by-Process as Insurance*. An "insurance" claim could have been included in the patent, e.g., In addition to the product claim ("A lubricating oil composition suitable as a crankcase lubricant in internal combustion engines comprising *** [an] ashless *** compound[ ]" and other ingredients), a product-by-process claim should have also been presented claiming, e.g., "[a] lubricating oil composition suitable as a crankcase lubricant in internal combustion engines ***produced from a mixture*** comprising *** [an] ashless *** compound[ ]" and other ingredients.

§ 17[a] Late Stage Conversion to True Product Protection

Whenever possible, it is always in the best interests of the patentee to have a true product claim that identifies the product, *per se*, as opposed to a product-by-process claim. Often, the structural identity of the product that is not known at the filing date *will* become known during the pendency of the application. In such a case, where the *product* is clearly and unequivocally identified *other than the structural formula* it should be possible, once the structural formula is known, to amend an original disclosure that "fingerprints" the identity of the structure without raising an issue of new matter.

In order to permit amendment of the application to include the structural formula to identify the product initially claimed in product-by-process format, it is essential that the product be "fingerprinted" in a manner to show that there is one and only one product that is the same as that later identified by structural formula. Beyond a working example of the preparation for the product, it would be helpful, for example, to include a spectral analysis of the product as a "drawing" figure accompanying the original specification as a fool proof "fingerprinting" of the product.

The structural formula in a true product claim is nothing more than a *label* for the product it identifies. Thus, whether the claim in question is a one to a "product", per se, or styled as a "product-by-process", the *product* is the object of the invention, and is identical no matter whether it is identified by a structural formula as in a pure product claim or as a product-by-process. Thus, in a regular "product" claim it is the three dimensional "thing", the compound, per se, that is claimed, while the two-dimensional structure, the formula, named in the claim is merely a "label" or "symbol" that is the *identifier* for the claimed compound: "[A] formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it." *Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, Inc.*, 630 F.2d 120, 128 (3rd Cir. 1980)(quoting *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)). *See also Commissioner of Patents v. Deutsche Gold-und-Silber-Scheideanstalt Vormals Roessler*, 397 F.2d 656, 662 (D.C. Cir., 1968)(same); *In re Herr*, 377 F.2d 610, 622 (C.C.P.A., 1967)(same).

As explained in greater detail in *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963):

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison. An assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous.

To be sure, an incomplete characterization of the product where the specification "recipe" for making the product allows for multiple possibilities may very well deny a patent applicant or patentee from substituting the correct structural formula for a product-by-process representation of the product. Where the original specification "fingerprints" the identity of the product, a subsequent identification of the structural formula matching that "fingerprint" should permit amendment of the specification to include the structural formula and, hence, permit a true product claim to be presented without loss of priority.

The law on incorporation by reference was established in *In re Fouche*, 439 F.2d 1237 (CCPA 1971), in the context of amendment to an original specification to identify a copending, still secret patent application where the serial number of the application was not included in the application as filed. The amendment adding the serial number was held to be free from new matter because the identity of the application was sufficiently fingerprinted:

"First, there is some merit to appellant's rebuttal arguments*** that it would be unreasonable to read the referring language as pertaining to anything but an earlier or concurrently filed United States application.

"Second, it is undisputed that, at the time of filing the present application, appellant in fact had on file in the Patent Office an application containing enough information to complete his disclosure as to the appealed claims. It is therefore clear that he had solved, as of his present filing date, any technical problems involved in making and using the claimed compositions. This is a major consideration in judging compliance with the first paragraph of § 112. See *In re Argoudelis*, 434 F.2d 1390, 58 CCPA (1971), and especially Judge Baldwin's concurring opinion therein.

"Third, application serial No. 459,921 [referenced without serial number] does in fact contain an "Example I" [cited in the specification] disclosing a method for preparing 10-(3-dimethylaminopropyl) dibenzo[a,d]cycloheptadiene. ***

"Fourth, there has been no showing by the Patent Office that there existed any other application to which the referring language could have pertained."

Fouche, 439 F.2d at 1240.

§ 17[b] *Ashless Dispersant Case,* Product-by-Process as Insurance

Even if the patentee has a good faith belief that he has identified the exact chemical composition of his invention, the reason why a product-by-process claim should be presented *in addition to* the product claim is seen from the *Ashless Disperant* Case, *Exxon Chemical Patents, Inc. v. Lubrizol Corp*., 64 F.3d 1553 (Fed. Cir. 1995)(Clevenger, J.), where the patentee had only a composition claim and did not provide a product-by-process claim.

If there is any doubt as to the identity of a final product, a prophylactic approach to safeguard protection is to provide *both* a true product claim *and* a product-by-process claim.

In *Exxon Chemical Patents, Inc. v. Lubrizol Corp*., 64 F.3d 1553 (Fed. Cir. 1995)(Clevenger, J.), the patentee's failure to properly claim the invention was literally a billion dollar mistake as this was the amount in controversy the patentee failed to gain because of the failure to present a product-by-process claim.

Each product claim included as an essential element of the claimed combination the presence of an "ashless dispersant". But, once the various ingredients specified in the claim were mixed together, the ashless dispersant "disappeared". The mistake was failing to provide a product-by-process claim.

The *Exxon* main claim is to a lubricant composition that requires an ashless dispersant. "[C]laim 1 is directed to '[a] lubricating oil composition suitable as a crankcase lubricant in internal combustion engines comprising' (1) a major amount of lubricating oil, (2) an ashless dispersant (*i.e.* one that neither contains nor is complexed with metal) in specified amounts of 'about 1 to 10 wt. %', (3) from

about 0.01 to 5.0 parts by weight of oil soluble ZDDP, (4) 5 to 500 parts per million by weight of added copper in the form of an oil soluble copper compound, and (5) magnesium or calcium detergent."

More completely, the claim in *Exxon v. Lubrizol* reads as follows:

"1. A lubricating oil composition suitable as a crankcase lubricant in internal combustion engines comprising:

"A. a major amount of lubricating oil;

"B. a dispersing amount of lubricating oil dispersant [which is an] ashless nitrogen or ester containing dispersant compound[ ] ***;

"C. ***oil soluble zinc dihydrocarbyl dithiophosphate wherein the hydrocarbyl groups contain from **1** to **18** carbon atoms;

"D. an antioxidant effective amount *** of added copper in the form of an oil soluble copper compound; and

"E. a lubricating oil detergent additive ****.

Exxon v. Lubrizol, 64 F.3d at 1556.

The accused infringing product provided a recipe of starting ingredients that 1:1 matched the claim limitations for the *product.* But, once the recipe was put together, *in situ* the ashless dispersant disappeared, converted into something else or otherwise destroyed. Therefore, the product lacked the required ashless dispersant element. Under the *Pennwalt* "all elements" rule, there was no infringement.

Circuit Judge Plager, in his concurrence, pointed out that the patentee *should have* included a product-by-process claim, which would have saved his case: "There is testimony in the record that indicates that it is not known exactly how the chemical complexing *** actually works. If this is so, then Exxon's burden, to prove that the chemical ingredients exist at some point in the accused composition in the claimed proportions, may be impossible of accomplishment. That could be said to argue in favor of an alternative construction of the claims, that what was meant was a process or product-by-process claim." *Exxon v. Lubrizol*, 64 F.3d at 1562-63 (Fed. Cir. 1995)(Plager, J., concurring).

Thus, "[i]n retrospect, it would appear that Exxon wishes it had product-by-process claims, and thus a 'recipe.' But [the court is] not free to read the claims as they might have been drafted, even if as drafted they do not accomplish what the inventor may have intended." *Id.* at 1563.

Judge Plager concludes: "Claim drafting is itself an art, an art on which the entire patent system today depends. The language through which claims are expressed is not a nose of wax to be pushed and shoved into a form that pleases and that produces a particular result a court may desire. The public generally, and in particular, the patentee's competitors, are entitled to clear and specific notice of what the inventor claims as his invention. That is not an easy assignment for those who draft claims, but the law requires it, and our duty demands that we enforce the requirement. There is no room in patent claim interpretation for the equivalent of the *cy pres* doctrine; that would leave the claiming process too indefinite to serve the purposes which lie at the heart of the patent system." *Id.*

§ 17[c] Scope of Product-by-Process for Infringement

§ 17[c][1] *Abbott v. Sandoz* Limitation to Product Produced by the Process

Is a product-by-process claim infringed when the *same product* is produced by a different process than identified in the claim? The United States has had a split view of this issue that was finally resolved *en banc* in *Abbott Laboratories v. Sandoz, Inc*., 566 F.3d 1282 (Fed. Cir. 2009)(en banc in relevant part)(Rader, J.):

This court *** addresses the proper interpretation of product-by-process claims in determining infringement. *** In reaching [its] conclusion, the trial court followed this court's opinion in *Atlantic Thermoplastics* [*Co. v. Faytex Corp.*, 970 F.2d 834 (Fed.Cir.1992) .] *** This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics.*

In *Atlantic Thermoplastics* [*Co. v. Faytex Corp.*, 970 F.2d 834 (Fed.Cir.1992)], this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method nonetheless infringed claim 26. Id. at 838. This court rejected the patentee's position. This court in Atlantic Thermoplastics construed product-by-process claims as limited by the process. Id. at 846-47.

This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. See *Smith v. Goodyear Dental Vulcanite Co*., 93 U.S. 486, 493 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224 (1880) ("[T]o constitute infringement of the patent, both the material of which the dental plate is made ... and the process of constructing the plate ... must be employed."); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) (BASF); *The Wood-Paper Patent*, 23 Wall. 566, 90 U.S. 566, 596 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp*., 304 U.S. 364 (1938); see also *Atl. Thermoplastics*, 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent

Appeals (see *In re Hughes*, 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims)),and the United States Court of Claims (see *Tri-Wall Containers v. United States*, 408 F.2d 748, 751 (Ct. Cl. 1969)), followed the same rule.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. See, e.g., *Hide-Ite Leather v. Fiber Prods.*, 226 F. 34, 36 (1st Cir.1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed.Cir.1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In BASF, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula $C_{14}H_8O_4$, but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. Id. at 309-10. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that arise when process limitations of product-by-process claims are ignored:

“[The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the

product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown. * * *

"If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.:

Id. at 310, 4 S.Ct. 455 (emphasis added).

After *BASF*, the Supreme Court continued to emphasize the importance of process steps in evaluating the infringement of product-by-process claims. See, e.g., *Plummer*, 120 U.S. at 448 ("[W]hatever likeness that may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); *Gen. Elec. Co*., 304 U.S. at 373 ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." (footnote omitted)).

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." *Atl. Thermoplastics*, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in In re Thorpe that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson*, 520 U.S. at 19. Although *Warner-Jenkinson* specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to product-by-process claims,

Warner-Jenkinson thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that *Scripps Clinic* is inconsistent with this rule, this court hereby expressly overrules *Scripps Clinic*.

The dissenting opinions lament the loss of a "right" that has never existed in practice or precedent—the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inventor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim—in this case process terms—are also the terms that show infringement.

Thus this court does not question at all whether product-by-process claims are legitimate as a matter of form. The legitimacy of this claim form was indeed a relevant issue in the nineteenth century when *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891), and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Customs and Patent Appeals—a court with virtually no jurisdiction to address infringement litigation—can shed little light on the enforcement of the only claim limitations that an applicant chooses to define the invention. Indeed, this court's venerable predecessor expressed its ambivalence towards the relevant infringement analysis:

"The policy of the Patent Office in permitting product-by-process type claims to define a patentable product, where necessary, has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se."

In re Bridgeford, 357 F.2d 679, 683 n. 5 (CCPA 1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. See also Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings.... [T]he courts uniformly hold that only a

product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co*., 304 U.S. 364 and *BASF*, 111 U.S. at 310).

Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny all product protection to such claims. See *In re Butler*, 37 F.2d 623 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case—a product defined by sophisticated PXRD technology—suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made.

Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 ¶ 6.

Thus, the Eastern District of Virginia correctly applied the rule that the recited process steps limit the product-by-process claims 2-5 for any infringement analysis.

§ 17[c][2] Minority View that Product made by Any Process Infringes

In *Abbott Laboratories v. Sandoz, Inc*., 566 F.3d 1282 (Fed. Cir. 2009)(en banc in relevant part)(Newman, J., dissenting), a forceful argument is presented that for purposes of patent infringement a product-by-process claim should cover the same product produced by a *different* process than recited in the claim:

> The court today acts en banc to overturn a century of precedent and practice, and holds that a new product that is difficult to describe without reference to how it was made, but that is nonetheless a new and unobvious product, cannot be protected as a product if its description is aided by reference to how it was made. Heretofore a new product whose structure was not fully known or not readily described could be patented as a product by including in the product description sufficient reference to how it can be made, to distinguish the new product from prior art products. Patentability was determined as a product, independent of any process reference in the claim, and validity and infringement were based on the product itself. This expedient for patenting products whose structure was not fully known at the time of filing the patent application has been called the "rule of necessity." It was pragmatic, fair, and just, for it attuned patent law and practice to the realities of invention.
>
> Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.

* * *

SUMMARY

Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product, independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A narrow but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, sua sponte and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the en banc court's rulings, as well as the procedure by which they were reached.

Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1299-1320 (Fed. Cir. 2009)(en banc in relevant part)(Newman, J., dissenting).

The Twenty Year War, Is it Over?

While there is presently apparent peace in the American law following *Abbott v. Sandoz* where the narrow view of scope of patent protection for product-by-process claims prevailed over the more than twelve thousand (12,000) word dissent of the losing jurist, 566 F.3d at 1282, 1299-1320 (Newman, J., dissenting). One must only marvel at the ant-like persistence of the dissenter who came to the Federal Circuit in 1984 upon her retirement from a top industry position and now is the longest serving member of the Federal Circuit in the history of that court.

The two protagonists have been at opposite ends of *en banc* decisions dating back to a decision when one of the protagonists had been a member of the court for only three months where he was part of the majority in *In re Dillon*, 919 F.2d 688, 699 (Fed. Cir. 1990)(Newman, J., joined by Cowen, Mayer, JJ., dissenting).
The differing views of the protagonists bubbled to the surface in the dispute over product-by-process claims where the senior of the two reached a conclusion that a product-by-process claim should be interpreted to cover the same product made by *any* process in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed.Cir. 1991)(Newman, J.). While *Scripps Clinic* became the binding precedent of the Federal Circuit, a year later a panel with the junior of the two jurists directly repudiated *Scripps Clinic*. *See Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 838 (Fed. Cir. 1992)(Rader, J.). The lack of collegial spirit was manifested by the judgement of the dean of the court, the late Giles Sutherland Rich, who proclaimed that the action of the junior member in *Atlantic Thermoplastics* "is not only insulting to the *Scripps* panel (Chief Judge Markey, Judge Newman and a visiting judge), it is mutiny. It is heresy. It is illegal." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279, 1281 (Fed. Cir. 1992)(Rich, J., dissenting from denial of rehearing en banc). The continued passion over this issue in the course of a generation is manifested by the dissent in *Abbott v. Sandoz* that runs over twelve thousand (12,000) words.

With the resignation from the bench of the junior protagonist there is now a vacuum. Is the Twenty Year War really over?

§ 17[c][3] Japan Adopts the Result of the Newman Dissent

In the *Pravastatin Sodium Case*, the Supreme Court of Japan has adopted the same result as proposed by Judge Newman in her dissent in the *Abbott* case: "[E]ven if a patent claim concerning a product invention recites the manufacturing process of a product, the technical scope of the patented invention should be determined to cover products that have the same structure and characteristics, etc., as those of the product made in accordance with the manufacturing process." *Pravastatin Sodium Case*, (Japan Supreme Court, June 5, 2015, Second Petty Bench, case Nos. 2012(ju)1204 and 2012(ju)2658); *see also* Dr. Shoichi Okuyama, *Pravastatin Sodium Case, Japan Product-by-Process Claiming Practice: Supreme Court Overrules the Grand Panel of the IP High Court* (June 8, 2015).

§ 17[d] Product-by-Process Patentability

Patentability of a product-by-process claim depends entire on whether the product that is defined by the process is patentable, and not whether the process defined in the product-by-process is described in the prior art. *See* § 16[e][4][a], *Validity is keyed to Product, not to Process for Making Product.* Because the Patent Examiner is a "paper chemist" without access to a laboratory to study the invention, the burden falls on patentee to show that the accused infringement is within the scope of the patentee's claim. *See* § 16[e][4][b], *Burden of Proof Shifts to the Patent Applicant.*

§ 17[d][1] Validity is keyed to Product, not to Process for Making Product

Patentability of a product-by-process claim depends upon whether the *product* is novel and unobvious over the prior art, whether or not the same *process* is used to make the prior art product:

"[E]ven though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

"Furthermore, '[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes.' *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 n 14 (Fed. Cir. 2009). However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim. *Id.* at 1370 ('a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim.').

"The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979) (holding 'interbonded by interfusion' to limit structure of the claimed composite and noting that terms such as 'welded,' 'intermixed,'

'ground in place,' 'press fitted,' and 'etched' are capable of construction as structural limitations.)."

MPEP § 2113, *Product-By-Process Claims* [R-08.2012], *Product-By-Process Claims are not Limited to the Manipulations of the Recited Steps, Only the Structure Implied by the Steps*.

§ 17[d][2] Validity tied to the Product, a British Viewpoint

Judge Birss provides an excellent summary of British and European law and practice of product-by-process claims in *Hospira UK Ltd. v. Genentech Inc.*, [2014] EWHC 3857 (Pat)(High Court 2014), where novelty in the process does not impart novelty for purposes of the patentability or validity of a product-by-process claim:

"125. Product by process claims are tricky. Before coming to the House of Lords in *Kirin Amgen* there are some background matters to deal with.

"126. One of the key problems which a system of patents for inventions has to handle is how to legislate for future inventive (non-obvious) developments. By definition they are often hard to foresee. One way this is done is to give inventors more or less complete freedom in the drafting of their patent applications. They can define the invention in a claim in any way and using any language they like so long as the definition is clear to a person skilled in the art and the invention satisfies various other criteria.

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"138. In *Kirin-Amgen* the House of Lords had to consider the novelty of an overt product by process claim. This is dealt with in the speech of Lord Hoffmann at paragraphs 86 to 101. A number of points arise. Lord Hoffmann dealt with the history of product by process claims and noted that the advantage they had before the 1977 Act was removed by s60(1)(c) (paragraphs 88-89). He noted that the idea that a process could confer novelty on a known product was not particularly logical since the history by which it was made is not an attribute which it carries around and makes it new (paragraph 88). He dealt with the EPO's practice starting from the 1980s, referring to the *IFF/claim Categories* T150/82 decision and the EPO's practice (paragraphs 90-91).

"He was puzzled by an earlier decision of the EPO relating to the patent in suit which appeared to be based on inconsistent findings of fact as to whether the process of making recombinant erythropoietin (rEPO) did or did not necessarily give rise to differences with known urinary erythropoietin (uEPO) (paragraphs 92-95) and noted that the trial judge (Neuberger J as he then was) had found as a fact that there was no necessary distinction between rEPO and uEPO (paragraph 96).

"139. In *Kirin-Amgen* ***. Lord Hoffmann *** held that a difference in the method of manufacturing did not make a product new and that was so as a matter of law. On that basis the claim could only be novel if the process definition gave the product a new characteristic of some kind. On the finding of fact in *Kirin-Amgen*, therefore claim 26 lacked novelty since the process did not necessarily do so. *** The UK should follow the approach of the EPO.

***

"145. [Based on the case law,] a product not made by the claimed process has been found not to infringe because it was not made by the claimed process while another product not made by the process has been found to render the claim lacking novelty despite the fact it was not made by the process. This is a little paradoxical but it shows the difficulties one can get into with product by process claims. A further puzzle is the following. What if, in *Kirin-Amgen*, the prior art uEPO had not been disclosed so as to be relevant for novelty but was something which was obvious? Presumably it would make the claim obvious for the same reason?

"146. On the other hand treating the point as a rule of novelty works in the EPO since the EPO is only concerned with validity. The EPO does not have to grapple with the meaning of these claims from the point of view of infringement. It is not obvious that an inventor who drafted his or her claim in the form of a product "obtained by" a process ever intended to cover other things or would be understood to be using language to mean that. The test for novelty is one thing but to ignore the clear words of the claim may result in it covering things which owe nothing to the inventor's technical contribution and risk insufficiency. It is hard to see how one can apply one of the key principles of construction emphasised by *Kirin-Amgen* itself, that the reader considers what the draftsman was using language to mean, in any other way.

"147. I derive the following principles from this consideration of the EPO and UK authorities:

"i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product.

"ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats "obtained by" language as "obtainable by" language, nevertheless as a matter of claim construction a claim to a product "obtained by" a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned."

Hospira UK v. Genentech , [2014] EWHC 3857 at ¶¶ 125, 126, 138, 139, 145-147.

§ 17[d][3] Burden of Proof Shifts to the Patent Applicant

If there is a close apparent relationship between the claimed product (defined by its process of manufacture) and the prior art, the burden is on the *patentee or patent applicant* to establish novelty and nonobviousness:

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.

In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be 'essentially free of alkali metal.' The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not 'essentially free of alkali metal' and therefore a different and unobvious product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental

tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

MPEP § 2113, *Product-By-Process Claims* [R-08.2012], *Once a Product Appearing to be Substantially Identical is Found and a 35 U.S.C. 102/103 Rejection Made, the Burden Shifts to the Applicant to Show an Unobvious Difference.*

The Patent Office justifies the shifting of the burden of proof to the applicant to establish patentability of a product-by-process invention because, in essence, the Examiner operates as a "paper chemist" without a laboratory; he is unable to establish through his own work whether an a product defined by the process of manufacture is or is not nonobvious:

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.

As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.' *In re Brown*, 459 F.2d 531, 535 (CCPA 1972). Office personnel should note that reliance on the alternative grounds of 35 U.S.C. 102 or 35 U.S.C. 103 does not eliminate the need to explain both the anticipation and obviousness aspects of the rejections."

MPEP § 2113, *Product-By-Process Claims* [R-08.2012], *The Use of 35 U.S.C. 102/103 Rejections for Product-By-Process Claims has been Approved by the Courts.*

§ 17[e] Rule of Necessity

At one time the United States followed the "rule of necessity" that permitted a product-by-process claim only where it was not possible to define a chemical product by its formula. This rule is no longer followed in the United States but *is* part of the practice in some other countries:

§17[e][1] Patent Office Repudiation of the Rule of Necessity

Historically, the United States followed the rule of necessity that barred presentation of a product-by-process claim without "[a] showing that the product cannot be described except by reference to the process of making it[.]" MPEP § 706.03(e), *Product by Process* (3rd ed. 1961)((citing *In re Dreyfuss and Whitehead*, 1935 C.D. 386 (1936)).

By the time of the next edition of the *Manual*, the policy had been liberalized: "An article may be claimed by a process of making it provided it is definite." Fourth edition (June 1979)(citations omitted). The current Fourteenth edition no longer even has a section devoted to product-by-process claims.

§ 17[e][2] EPO Adoption of the Rule of Necessity

"Although normally a patent is drafted by the inventor 'in words of his own choosing', the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they mean no other way of defining a particular characteristic of the product in question." *Hospira UK Ltd. v. Genentech Inc.*, [2014] EWHC 3857 ¶ 147(iii), (Pat)(High Court 2014)(Birss, J.).

As explained earlier in this opinion:

"[¶] 135. The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee. This is a decision based on policy. Such claims present clarity problems and are best avoided but if there is no alternative way of defining the characteristic in question, then they will be permitted.

"[¶] 136. But despite their apparently esoteric nature (even by the standards of patents) product by process language is actually quite common and hardly remarked upon. ***."

Id. at ¶¶ 135-136.

§ 17[e][3] Japan Adoption of the Rule of Necessity

In the *Pravastatin Sodium Case*, the Supreme Court of Japan has adopted the approach taken in Europe that follows the rule of necessity:

"[W]hen patent claims concerning a product invention recite the manufacturing process of a product, the claims would satisfy the requirement [that] "the invention be clear" according to Article 36(6)(ii), Patent Act, only if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing." *Pravastatin Sodium Case*, (Japan Supreme Court, June 5, 2015, Second Petty Bench, case Nos. 2012(ju)1204 and 2012(ju)2658); *see also* Dr. Shoichi Okuyama, *Pravastatin Sodium Case, Japan Product-by-Process Claiming Practice: Supreme Court Overrules the Grand Panel of the IP High Court* (June 8, 2015).

§ 17[f] Plural Product-by-Process Claims of Varying Scope

The Patent Office acknowledges the right of the patent applicant to present multiple product-by-process claims in a single application:

"An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms." MPEP § 2173.05(p), *Claim Directed to Product-By- Process or Product and Process* (citing *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972)).

§18. "Means"-Defined Functional Elements

"Means for" terminology is a statutory trigger to invoke the presumption that a functional claim should be interpreted according to 35 USC § 112(f) of the *Leahy Smith America Invents Act*:

"ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a *means ... for* performing a specified function without the recital of structure [or] material … in support thereof, and such claim shall be construed to cover the corresponding structure [or] material … described in the specification and equivalents thereof."

The original "means" provision was styled as 35 USC § 112 ¶ 3 as part of the 1952 Patent Act. With the addition in 1965 of three further paragraphs preceding the "means" provision, the final paragraph of Section 112 became paragraph 6.

"Means for" and other functional language to define an element of a claim has been a part of the American patent law since the nineteenth century, but was introduced as a *statutory* feature only in the 1952 Patent Act. The principal draftsman of this provision of the 1952 Patent Act explained "that a considerable body of case law, if not the preponderance thereof, before [*Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946),] interpreted broad statements of structure, e. g., 'means,' plus a statement of function in the manner now sanctioned by the statute. See, e. g., *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 558 (1898)."

In re Fuetterer, 319 F.2d 259, 264 n.11 (CCPA 1963)(Rich, J.).

The Supreme Court in the generation leading up to the 1952 Patent Act had numerous patent cases where a claim reciting an element with "means for" language was used. *See, e.g., Saranac Automatic Mach Corporation v. Wirebounds Patents Co*., 282 U.S. 704, 705 n.1 (1931)(quoting U.S. Patent 1,128,145, Claim 25, and U.S. Patent 1,128,144, Claim 6, reciting "means for" elements); *Permutit Co v. Graver Corp*., 284 U.S. 52, 58 n.5 (1931)(quoting claim 5 reciting "means for" element); *Keystone Driller Co v. Northwest Engineering Corp.*, 294 U.S. 42, 47 (1935)(quoting "means for" usage in claims); *Altoona*

Publix Theatres v. American Corp., 294 U.S. 477, 479-80 (1935)("claim 13 [ ] was for a combination for a means for projecting a narrow line of light upon and through the moving film to a photoelectric cell in sound reproduction"); *United States v. Esnault-Pelterie*, 299 U.S. 201, 203-04 (1936)(quoting claim 5 reciting "means for" element); *Textile Machine Works v. Louis Hirsch Textile Machines, Inc*., 302 U.S. 490, 494 (1938)(quoting claim 5 reciting "means for" usage); *Williams Mfg. Co v. United Shoe Machinery Corp*., 316 U.S. 364, 388 (1942)(citing claim 164; claim recites "means for" elements);*Marconi Wireless Telegraph Co of America v. United States.* 320 U.S. 1, 52 (1943)(quoting claims; reciting "means for" elements). Lower courts also used "means for" terminology, e.g., *Lewis v. Merritt, Chapman & Scott Corp*., 3 F.2d 66 (E.D.N.Y., 1924)(quoting claims 2 and 5 using "means for" terminology); *Auto Hone Co. v. Hall Cylinder Hone Co.,* 3 F.2d 479, 482 (N.D. Ohio 1924) (same, quoting claim 6); *International Banding Mach. Co. v. American Bander Co*., 4 F. 2d 726, 730 (S.D.N.Y. 1924)(same, quoting claim 97). *aff'd*, 9 F.2d 606 (2nd Cir. 1925); *McLaren Products Co. v. Cone Co. of America*, 7 F.2d 120, 120-22 (E.D.N.Y. 1925) (same). Nineteenth century cases also used "means for" definitions. *See Burr v. Duryee,* 68 U.S. (1 Wall.) 531, 548 (1863)(summary not part of the opinion)(quoting claim language "means for directing the fur-bearing current"). Specification support was also a problem for "means for" claims before the 1952 Patent Act. *International Banding*, 9 F.2d at 612-13 (L. Hand, J., dissenting).

The principal draftsman explained that "[t]he record is clear on why [the statutory "means" provision] was enacted. In *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946), the Supreme Court held that means-plus-function language

could not be employed at the exact point of novelty in a combination claim. Congress enacted [the statutory "means" provision] to statutorily overrule that holding. See *In re Fuetterer*, 319 F.2d 259, 264 n. 11 (CCPA 1963) (noting that it was Congress's intent to restore the law regarding broad functional language in combination claims to its state prior to Halliburton)." *In re Donaldson Co.*, 16 F.3d 1189, 1194 (Fed. Cir. 1994) (en banc)(Rich, J.).

Merely because the statutory provision *exists* and *can* be used by an applicant is not, however, a reason *why* this provision should be used in daily practice. It is on the one hand easy to write "means for" in a patent claim, but it is extremely challenging to draft supporting specification language to provide for a proper scope of protection and to avoid invalidity on the basis of indefiniteness. *See* § 18[a], *"Means" Defined Elements should be Avoided.*

"Means" language is particularly ill advised for a domestic *first filing* which is to be the basis for Paris Convention priority filings around the world: No other country honors the American statutory scheme. *See* §18[a][1], *Conflict with All Other Patent Laws of the World.* Even disregarding the difficulties the applicant will face in obtaining a priority right abroad keyed to the unique American draftsmanship needed to support a "means" claim, *domestically* the applicant who chooses the "means" claiming route will invariably gain a *narrower* scope of protection: A means claims *exclude* all examples of the means-defined element *other than* the disclosed embodiment in the specification and equivalents of the disclosed embodiment (or embodiments). *See* §18[a][2], *"Means" Interpretation Provides Narrower Protection.*

Fortunately, the applicant can easily escape the pitfalls of the statutory "means" interpretation of claims by taking two precautions:

First, the word "means" should never be used in the claims because use of the term "means" is the statutory trigger of a *presumption* that the "means"-defined element will be interpreted under the "means" paragraph of the statute, as explained by the author of that provision in *In re Donaldson Co.*, 16 F.3d 1189, 1195(Fed.Cir.1994) (en banc)(Rich, J.); *see* § 18[b][1], *The En Banc Explanation in Donaldson; see also Williamson v. Citrix Online, LLC.*, __ F.3d __, __ (Fed. Cir. 2015)(en banc in relevant part)(Linn, J.), § II-C-1, *Applicability of 35 U.S.C. § 112, para. 6;* §18[b][3], *Williamson Presumption when "Means" Language is Used.*

Second, the specification should include a recitation of *structure* that exemplifies the "means"-defined element. Absent recitation of such structure, even without use of the "means" term, the "means" statutory provision will be used to interpret the element. *See* §18[c][2], *Absence of Structure to Rebut the "Means" Presumption.*

Further complicating usage of "means"-defined elements is the continued confusion within the patent community itself. One of the members of the *en banc* court in *Williamson* sees the need for a deeper study of "fundamental' issues. *See* §17[d][1], *"Sidestep[ping] Fundamental Issues"* (discussing *Williamson v. Citrix Online*, __ F.3d at ___ (Fed. Cir. 2015)(en banc in relevant part)(Reyna, J., concurring-in-part, dissenting-in-part, and additional views)). More challenging to parse is the lengthy separate opinion by the senior member of the Court. *See* §17[d][2], *Unique Concerns over the Means Presumption* (quoting *Williamson v. Citrix Online, LLC.*, __ F.3d at ___ (Fed. Cir. 2015)(en banc in relevant part)(Newman, J., dissenting)).

One of the major problems for "means" claiming that should dissuade the prospective first time user of this claim form is that it is more difficult to *support* this type of claim than any other claim form. *See* § 18[e], *Algorithm to Support a "Means"-Defined Element* (quoting *Blackboard, Inc. v. Desire2Learn, Inc*., 574 F.3d 1371 (Fed. Cir. 2009)). The problem of supporting structure is particularly acute where software is defined in terms of "means": Numerous attempts have been made (unsuccessfully) to enforce such claims where the specification failed to disclose a supporting algorithm. *See* §18[e][1], *Algorithm Needed for Software Inventions.* There are rare exceptions. *See* §18[e][3], *"Katz Exception" with no Need for Algorithm Disclosure.*

§ 18[a] "Means" Defined Elements should be Avoided

A first filing should *always* avoid usage of a "means"-defined element as part of a worldwide filing plant where that first filing will be basis for Paris Convention priority around the world. Even if the application is not to be filed globally, the default choice should be *against* employing a "means"-defined element.

§18[a][1] Conflict with All Other Patent Laws of the World

In the more than sixty years since the first introduction of the statutory "means"-defined claim element in the 1952 Patent Act not one single country has joined with the United States to employ this unique claim interpretation system.

Thus, a "perfectly" tailored set of claims and supporting specification based upon a "means"-defined claim element will *not* be optimally suited as a priority application for foreign protection because the unique interpretation scheme of 35 USC § 112(f) is *not* part of any foreign patent law.

§18[a][2] "Means" Interpretation Provides Narrower Protection

A properly drafted "means"-defined element provides *narrower* coverage than a regular definition of the same term. This was made clear only in 1994 in the leading cases, *In re Donaldson Co.,* 16 F.3d 1189 (Fed. Cir. 1994) (en banc)(Rich, J.), and *In re Alappat,* 33 F.3d 1526 (Fed.Cir.1994) (en banc)(Rich, J.). Senior practitioners from the time before *Alappat* and *Donaldson* often mistakenly thought that the reference to coverage of "equivalents" in the statute meant that "means"-defined elements received *broader* protection than otherwise is possible.

But, the statute *limits* the scope of protection to a "means"-defined element to *exclude* all embodiments that are *other than* the *disclosed* embodiment – and equivalents of that *disclosed* embodiment. Thus, under what is now 35 USC § 112(f) of the *Leahy Smith America Invents Act* a "means"-defined element is *limited* to "to cover the … structure [or] material… described in the specification *and equivalents* thereof."

§ 18[b] "Means for" Triggers the Statutory Presumption

§ 18[b][1] The *En Banc* Explanation in *Donaldson*

The late Giles Sutherland Rich, the principal draftsman of the "means for" provision of the 1952 Patent Act, explains the usage of the "means" term: "[T]he PTO [is] required by statute to look to [the] specification and construe the 'means' language recited in *** [the claim] as limited to the corresponding structure disclosed in the specification and equivalents thereof." *In re Donaldson Co.,* 16 F.3d 1189, 1195(Fed.Cir.1994) (en banc)(Rich, J.).

As explained two years after *Donaldson*, "[t]he question whether a claim element triggers section 112(6) is ordinarily not a difficult one. Claim drafters conventionally use the preface "means for" *** when they intend to invoke section 112(6), and there is therefore seldom any confusion about whether section 112(6) applies to a particular element." *Greenberg v. Ethicon Endo-Surgery, Inc*., 91 F.3d 1580, 1583 (Fed. Cir. 1996)(Bryson, J.).

The "means for" language introduced into the 1952 Patent Act did not come from thin air but was taken from a major thread of application drafting that was dominant in the generation leading up to this legislation. The principal draftsman of the statutory provision explained "that a considerable body of case law, if not the preponderance thereof, before [*Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946),] interpreted broad statements of structure, e. g., 'means,' plus a statement of function in the manner now sanctioned by the statute. See, e. g., *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 558 (1898)." *In re Fuetterer*, 319 F.2d 259, 264 n.11 (CCPA 1963)(Rich, J.). *See also Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 548 (1863)(summary not part of the opinion)(quoting claim language "means for directing the fur-bearing current"); *Marconi Wireless Telegraph Co. of America v. United States,* 320 U.S. 1, 38 1943)(claiming "means for adjusting the two transformer-circuits in electrical resonance with each other")(emphasis supplied).

§ 18[b][2] The Patent Office Understanding of the Presumption

The Patent Office understands the "means for" language as a trigger of what is now 35 USC § 112(f). *See* MPEP § 2181, *Identifying and Interpreting a 35 U.S.C. 112(f) *** Limitation* (4th ed. 2014) ("[A] claim limitation is presumed to invoke 35 U.S.C. 112(f) *** when it explicitly uses the term 'means' *** and includes functional language. That presumption is overcome when the limitation further includes the structure necessary to perform the recited function. *TriMed, Inc. v. Stryker Corp*., 514 F.3d 1256, 1259-60 (Fed. Cir. 2008) ('Sufficient structure exists when the claim language specifies the exact structure that performs the function in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure.'); see also *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1376 (Fed. Cir. 2003).")

§18[b][3] *Williamson* Presumption when "Means" Language is Used

En banc, the Federal Circuit in *Williamson v. Citrix Online, LLC.*, __ F.3d __, __ (Fed. Cir. 2015)(en banc in relevant part)(Linn, J.), § II-C-1, *Applicability of 35 U.S.C. § 112, para. 6,* provides clarification as to when a court should employ "means" interpretation of a claim:

"In enacting [what is now 35 USC § 112(f)], Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed, namely, by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof. *See Northrop Grumman Corp. v. Intel Corp*., 325 F.3d 1346, 1350 (Fed. Cir. 2003).

"To determine whether § 112, para. 6 applies to a claim limitation, our precedent has long recognized the importance of the presence or absence of the word 'means.' In *Personalized Media Communications, LLC v. International Trade Commission*, building upon a line of cases interpreting § 112, para. 6,[4] we stated that the use of the word 'means' in a claim element creates a rebuttable presumption that § 112, para. 6 applies. 161 F.3d 696, 703-04 (Fed. Cir. 1998) ***

"Merely because a named element of a patent claim is followed by the word 'means,' however, does not automatically make that element a 'means-plus-function' element under 35 U.S.C. § 112, ¶ 6.***

"[T]he essential inquiry is not merely the presence or absence of the word "means" but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Greenberg* [*v. Ethicon Endo-Surgery, Inc*., 91 F.3d 1583 (Fed. Cir. 1996)]("What is important is . . . that the term, as the name for structure, has a reasonably well understood meaning in the art."). When the claim uses the word "means," our cases have been consistent in looking to the meaning of the language of the limitation in assessing whether the presumption is overcome. We have also traditionally held that when a claim term lacks the word "means," the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite[] sufficiently definite structure" or else recites "function without reciting sufficient structure for performing that function." *Watts v. XL Sys., Inc*., 232 F.3d 877, 880 (Fed. Cir. 2000)."

* * *

"The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Greenberg*, 91 F.3d at 1583. When a claim term lacks the word "means," the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to "recite sufficiently definite structure" or else recites "function without reciting sufficient structure for performing that function." *Watts*, 232 F.3d at 880. The converse presumption remains unaffected:

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[4] *See, e.g., Laitram Corp. v. Rexnord, Inc*., 939 F.2d 1533 (Fed. Cir. 1991); *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580 (Fed. Cir. 1996); *Cole v. Kimberly-Clark Corp*., 102 F.3d 524 (Fed. Cir. 1997); *Mas-Hamilton Group v. LaGard, Inc*., 156 F.3d 1206 (Fed. Cir. 1998); *Unidynamics Corp. v. Automatic Prods. Int'l, Ltd.*, 157 F.3d 1311 (Fed. Cir. 1998).

"use of the word 'means' creates a presumption that § 112, ¶ 6 applies." *Personalized Media*, 161 F.3d at 703."

§18[b][4] Converse Presumption without "Means" Language

As stated by the *en banc* Court in *Williamson:*

"Applying the converse [to the presumption that use of the term 'means' triggers a statutory 'means' interpretation], we stated that the failure to use the word 'means' also creates a rebuttable presumption—this time that § 112, para. 6 does not apply. *Id.* We have not, however, blindly elevated form over substance when evaluating whether a claim limitation invokes § 112, para. 6:

" '***[M]erely because an element does not include the word 'means' does not automatically prevent that element from being construed as a means-plus-function element.'

"Cole v. Kimberly-Clark Corp., 102 F.3d 524, 531 (Fed. Cir. 1996); *see also Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996) ('We do not mean to suggest that section 112(6) is triggered only if the claim uses the word 'means.'').

"In making the assessment of whether the limitation in question is a means-plus-function term subject to the strictures of § 112, para. 6, our cases have emphasized that the essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Greenberg*, 91 F.3d at 1583 ('What is important is . . . that the term, as the name for structure, has a reasonably well understood meaning in the art.').When the claim uses the word 'means,' our cases have been consistent in looking to the meaning of the language of the limitation in assessing whether the presumption is overcome. We have also traditionally held that when a claim term lacks the word 'means,' the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite[ ] sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.' *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000).

***

"***Henceforth, we will apply the presumption as we have done [under earlier case law] without requiring any heightened evidentiary showing and expressly overrule the characterization of that presumption as 'strong.' We also overrule the strict requirement of 'a showing that the limitation essentially is devoid of anything that can be construed as structure.'

"The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. *Greenberg*, 91 F.3d at 1583. When a claim term lacks the word 'means,' the presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.' *Watts*, 232 F.3d at 880."

§ 18[c] Structure Focused on the Stated Function

The definition of a means-defined element in a claim is based upon what is *disclosed* in the specification which is "Part II" of a two step inqury. As explained by Circuit Judge Linn in *Williamson v. Citrix Online, LLC,* __F.3d __ (Fed Cir. 2015):

Construing a means-plus-function claim term is a two-step process. The court must first identify the claimed function. *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). Then, the court must determine what structure, if any, disclosed in the specification corresponds to the claimed function. Where there are multiple claimed functions, as we have here, the patentee must disclose adequate corresponding structure to perform all of the claimed functions. *Id*. at 1318-19. If the patentee fails to disclose adequate corresponding structure, the claim is indefinite. *Id*. at 1311-12.

***

Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim. *Id*. (citing *B. Braun Med., Inc. v. Abbott Labs*., 124 F.3d 1419, 1424 (Fed. Cir. 1997)). Even if the specification discloses corresponding structure, the disclosure must be of 'adequate' corresponding structure to achieve the claimed function. *Id*. at 1311-12 (citing *In re Donaldson Co*., 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc)). Under 35 U.S.C. § 112, paras. 2 and 6, therefore, if a person of ordinary skill in the art would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim, a means-plus-function clause is indefinite. *Id*. at 1312 (citing *AllVoice Computing PLC v. Nuance Commc'ns, Inc*., 504 F.3d 1236, 1241 (Fed. Cir. 2007)).

Circuit Judge O'Malley in *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302 (Fed. Cir., 2012), provides a parallel view of the law:

Construction of a means-plus-function limitation includes two steps. 'First, the court must determine the claimed function. Second, the court must identify the corresponding structure in the written description of the patent that performs the function.' *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1332 (Fed.Cir.2006) (internal citations omitted). ***[T]he inquiry on appeal is whether the specification adequately discloses a corresponding structure that performs the function associated with the 'access means' limitation.

A structure disclosed in the specification qualifies as a 'corresponding structure' if the specification or the prosecution history 'clearly links or associates that structure to the function recited in the claim.' *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed.Cir.1997). Even if the specification discloses a 'corresponding structure,' the disclosure must be adequate; the patent's specification must provide 'an adequate disclosure showing what is meant by that [claim] language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.' *In re Donaldson Co*., 16 F.3d 1189, 1195 (Fed.Cir.1994) (en banc). Under 35 U.S.C. § 112 ¶ 2 and ¶ 6, therefore, 'a means-plus-function clause is indefinite if a person of ordinary skill in the art would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim.' *AllVoice Computing PLC v. Nuance Commc'ns., Inc.*, 504 F.3d 1236, 1241 (Fed.Cir.2007) (citing *Atmel Corp. v. Info. Storage Devices, Inc*., 198 F.3d 1374, 1381–82 (Fed.Cir.1999)).

While it is undisputed that the question of whether a claim is indefinite is based on how the claim limitation would be understood by one of skill in the art, 'the testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification.' *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.,* 412 F.3d 1291, 1302 (Fed.Cir.2005); *see also Biomedino, LLC v. Waters Techs. Corp.,* 490 F.3d 946, 950–53 (Fed.Cir.2007). The prohibition against using expert testimony in this manner is a direct consequence of the requirement that the specification itself adequately disclose the corresponding structure. *AllVoice Computing,* 504 F.3d at 1240 ('The test for definiteness asks whether one skilled in the art would understand the bounds of the claim when read in light of the specification.' (citation omitted)).

§ 18[c][1] Correlation of Structure to Stated Function

An applicant setting forth a means-defined element must *identify the structure* set forth in the specification that preforms the "means"-defined function.

As explained in *Micro Chem,* "[a]pplication of § 112, ¶ 6 requires identification of the structure in the specification which performs the recited function. See *Rodime PLC v. Seagate Tech., Inc.,* 174 F.3d 1294, 1302 (Fed. Cir. 1999). Therefore, *§ 112, ¶ 6 requires both identification of the claimed function and identification of the structure in the written description necessary to perform that function.* The statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim." *Micro Chem., Inc. v. Great Plains Chem. Co.,* 194 F.3d 1250, 1257-58 (Fed.Cir.1999) (emphasis added).

Or, as stated by Judge Dyk, "[w]hen construing functional claims under § 112 ¶ 6, "[t]he statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim." *Micro Chem., Inc. v. Great Plains Chem. Co.,* 194 F.3d 1250, 1258 (Fed.Cir.1999)

("[T]he district court erred ... by incorporating unrecited functional limitations into the claims."); *see also Globetrotter Software, Inc. v. Elan Computer Grp.*, 236 F.3d 1363, 1367 (Fed.Cir.2001) (The structure disclosed in the specification must be necessary to perform 'the function described in the claim.') (citing *Micro Chem.*, 194 F.3d at 1258)." *In re Teles AG Informationstechnologien*, 747 F.3d 1357, 1367-68 (Fed. Cir., 2014)(Dyk, J.).

In *Australia Pty Ltd. v. International Game Technology*, 521 F.3d 1328 (Fed.Cir.2008), the court emphasizes that it is the *disclosure* of the structure that is critical, and not whether a structure would be obvious to a worker skilled in the art. Thus:

"[I]n *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1380 (Fed.Cir.1999), the court embraced the proposition that 'consideration of the understanding of one skilled in the art in no way relieves the patentee of adequately disclosing sufficient structure in the specification.' It is not enough for the patentee simply to state or later argue that persons of ordinary skill in the art would know what structures to use to accomplish the claimed function. The court in *Biomedino, LLC v. Waters Technologies Corp.*, 490 F.3d 946, 953 (Fed.Cir.2007), put the point this way: 'The inquiry is whether one of skill in the art would understand the specification itself to disclose a structure, not simply whether that person would be capable of implementing that structure.'"

Aristocrat Technologies, 521 F.3d at 1336-37.

§18[c][2] Obviousness is not Disclosure of "structure"

"Means"-defined software should be supported by disclosure of an algorithm in the specification even though, *arguendo,* it may very well be within the skill of a worker in the art how to create an algorithm that would satisfy the enablement requirement of 35 USC § 112(a). The reason for this distinction is because the issue in the first instance for a "means"-defined software element is *not* a question of *enablement.* Rather, the issue is one of the *definition* of the invention because the "means"-defined element has a scope of protection limited to "the corresponding structure *** *described in the specification* and equivalents thereof." 35 USC § 112(f)(emphasis added). Circuit Judge Bryson explains the distinction in *Blackboard, Inc. v. Desire2Learn Inc.,* 574 F.3d 1371 (Fed.Cir.2009). He explains the unique definitional challenge for a "means"-defined claim element. Without disclosure of structure in the specification, there is no way to determine the scope of the "means"-defined element because the *disclosed* structure is at the heart of the definition of the scope of protection: As explained in *Blackboard v. Desire2Learn:*

> Because th[e] limitation is written in 'means-plus-function' form, it covers only 'the corresponding structure ... described in the specification and equivalents thereof.' 35 U.S.C. § 112, ¶ 6.
>
> * * *
>
> The specification contains no description of the structure or the process that the access control manager uses to perform the 'assigning' function. Nor has [the patentee] ever suggested that the 'access control manager' represents a particular structure defined other than as any structure that performs the recited function. In fact, before the district court, counsel for [the patentee] defined the term 'access control manager' in precisely those terms. He stated, 'We suggest that the corresponding structure for [the function of assigning a level of access to and control of each data file] is the access control manager. That's not really a revolutionary thought. The access control manager manages access control.'

Counsel also stated of the access control manager that 'the name of it pretty much describes what it does. It assigns a level of access to and control of a user's role in a course.' [patentee]'s expert made clear that he did not regard the term 'access control manager' as limited even to software. He stated, 'Although the access manager in Figure 1 is described as software, there is nothing in the [ ] patent specification that would limit the performance of the access manager's functions to software; one of ordinary skill in the art would know that hardware could be used.' In other words, the access control manager, according to [the patentee], is any computer-related device or program that performs the function of access control.

In *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 521 F.3d 1328, 1331 (Fed.Cir.2008), we addressed the question whether a general reference to 'a standard microprocessor-based gaming machine with appropriate programming' constituted a sufficient disclosure of structure to support a claimed function in a means-plus-function claim. We concluded that it did not. First, we explained that '[t]he point of the requirement that the patentee disclose particular structure in the specification and that the scope of the patent claims be limited to that structure and its equivalents is to avoid pure functional claiming.' *Id.* at 1333. Without so limiting a claim, we noted, 'the patentee has not paid the price but is attempting to claim in functional terms unbounded by any reference to structure in the specification.' *Id.* (citations omitted). We then applied those teachings to the patentee's assertion that a reference to a general purpose computer could satisfy that standard. We noted that 'any general purpose computer must be programmed' and pointed out that relying on such general structure is equivalent to saying 'that the function is performed by a computer that is capable of performing the function.' *Id.* at 1334. We also considered and rejected the patentee's assertion that language describing when the computer would perform the function at issue constituted a sufficient description of the structure for performing the function. Such language, we explained, 'describes an outcome, not a means for achieving that outcome.' Id.

In *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed.Cir.2008), we again addressed a patentee's argument that reference to a computer provides sufficient structure for a claim drafted in means-plus-function form. In Net MoneyIN, the computer was not a general purpose computer; the patentee contended that the reference to a 'bank computer' provided sufficient structure to support the function of 'generating an authorization indicia in response to queries containing a customer account number and amount.' *Id.* at 1365. The patentee argued that 'a person skilled in the art would know that such a computer would be programmed to compare account data and amount data to those data structures and

generate an authorization indicia if credit were available.' *Id.* at 1366-67. We rejected that argument and explained that when a computer is referenced as support for a function in a means-plus-function claim, there must be some explanation of how the computer performs the claimed function:

"To avoid purely functional claiming in cases involving computer-implemented inventions, we have consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor. Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to the corresponding structure, material, or acts that perform the function, as required by section 112 paragraph 6. Thus, in a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm. Consequently, a means-plus-function claim element for which the only disclosed structure is a general purpose computer is invalid if the specification fails to disclose an algorithm for performing the claimed function."

Id. at 1367 (citations omitted). Because there was no disclosed algorithm in that case, we held that the claims were invalid for lack of a sufficient recitation of structure. Id.; see also *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1340-41 (Fed.Cir.2008) ('Simply reciting `software' without providing some detail about the means to accomplish the function is not enough.').

[The patentee] argues that the specification in this case contains more disclosure of the structure that performs the access control functions than did the specifications in *Aristocrat* and *Net MoneyIN*. It points to the sentence in the specification that states, 'Education support system 100 provides multiple levels of access restrictions to enable different types of users to effectively interact with the system (e.g. access web pages, upload or download files, view grade information) while preserving confidentiality of information.' [citation omitted] That sentence, however, merely states that the access control manager enables different types of users to interact with the system in a manner that preserves confidentiality (i.e., it works as intended). Like the specification in *Aristocrat*, that language 'simply describes the function to be performed.' 521 F.3d at 1334. It says nothing about how the access control manager ensures that those functions are performed. As such, the language 'describes an outcome, not a means for achieving that outcome.' *Aristocrat*, 521 F.3d at 1334.

[The patentee] argues that the process of putting together control lists through software is well known to a person of ordinary skill in the art because access control lists 'have been around for a long time and everyone of ordinary skill in the field of this invention would know how to construct one given the understanding conveyed in the specification about the entry of files into the system, and which roles have access to which types of files.' That argument, however, conflates the definiteness requirement of section 112, paragraphs 2 and 6, and the enablement requirement of section 112, paragraph 1. The fact that an ordinarily skilled artisan might be able to design a program to create an access control list based on the system users' predetermined roles goes to enablement. The question before us is whether the specification contains a sufficiently precise description of the 'corresponding structure' to satisfy section 112, paragraph 6, not whether a person of skill in the art could devise some means to carry out the recited function.

[Patentee]'s argument that a person skilled in the art could readily fashion a computer-based means for performing the 'assigning' function is the same as the argument that we rejected in *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205 (Fed.Cir.2003). There, the patentee sought to overcome a finding of indefiniteness by relying on expert testimony that a software programmer with ordinary skill in the pertinent art would be aware of programs that could be used to perform the recited function. The court explained, however, that the expert's testimony was not directed at the correct inquiry. The court stated:

"The correct inquiry is to look at the *disclosure* of the patent and determine if one of skill in the art would have understood that *disclosure* to encompass software for digital-to-digital conversion and been able to implement such a program, not simply whether one of skill in the art would have been able to write such a software program.... It is not proper to look to the knowledge of one skilled in the art apart from and unconnected to the disclosure of the patent."

344 F.3d at 1212 (emphasis in original).

[Patentee]'s argument also parallels the argument that was rejected in *Net MoneyIN*, i.e., that the recitation of structure was sufficient because a person skilled in the art would know how to program a bank computer to generate 'an authorization indicia.' 545 F.3d at 1367. A patentee cannot avoid providing specificity as to structure simply because someone of ordinary skill in the art would be able to devise a means to perform the claimed function. To allow that form of claiming under section 112, paragraph 6, would allow the patentee to claim all possible means of achieving a function. *See Atmel Corp. v. Information Storage*

Devices, Inc., 198 F.3d 1374, 1380 (Fed.Cir.1999) ('consideration of the understanding of one skilled in the art in no way relieves the patentee of adequately disclosing sufficient structure in the specification').

That ordinarily skilled artisans could carry out the recited function in a variety of ways is precisely why claims written in 'means-plus-function' form must disclose the particular structure that is used to perform the recited function. By failing to describe the means by which the access control manager will create an access control list, [the patentee] has attempted to capture any possible means for achieving that end. Section 112, paragraph 6, is intended to prevent such pure functional claiming. *Aristocrat*, 521 F.3d at 1333. We thus agree with the district court that the [ ] patent discloses insufficient structure to perform the function of 'assigning a level of access to and control of each data file based on a user of the system's predetermined role in a course.'

Blackboard v. Desire2Learn, 574 F.3d at1382–85.

Three years after *Blackboard v. Desire2Learn* the same issue was presented in *DealerTrack, Inc. v. Huber*, 674 F.3d 1315 Fed. Cir. 2012), where a "means"-defined software invention lacked disclosure of an algorithm to perform a function of that software:

"[It] is clear that [the claims] recite an additional function for the 'central processing means' to perform—i.e., the function of 'further provid[ing] for tracking pending credit applications.' … [T]he appropriate structure for the 'central processing means' limitation must include the algorithms disclosed in the specification that 'implement[ ] and control[ ]' the recited functions that the 'central processing means' is required to perform. However, the [ ] specification discloses no algorithm pursuant to which the 'central processing means' could perform the claimed function of 'tracking.' The 'central processing means' term is therefore indefinite, as used in [the claims], for failure to recite sufficient structure to perform its claimed functions. See *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1382 (Fed.Cir.2009); *Aristocrat* [*Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed.Cir.2008)]; *WMS Gaming*[, *Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed.Cir.1999)]."

DealerTrack v. Huber, 674 F.3d at 1330.

§ 18[d] Algorithm to Support a "Means"-Defined Element

As seen from *Blackboard, Inc. v. Desire2Learn, Inc*., 574 F.3d 1371 (Fed. Cir. 2009), it is axiomatic that a "means"-defined element must have supporting structure set forth in the specification. As explained in that case:

"[Where a] limitation is written in 'means-plus-function' form, it covers only 'the corresponding structure ... described in the specification and equivalents thereof.' 35 U.S.C. § 112, ¶ 6. * * *

"It is well settled that 'if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language.' *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed.Cir. 1994) (en banc). If the specification does not contain an adequate disclosure of the structure that corresponds to the claimed function, the patentee will have 'failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112,' which renders the claim invalid for indefiniteness. *Id."*

Blackboard v. Desire2Learn, 574 F.3d at 1382.

§18[d][1] Algorithm Needed for Software Inventions

It is difficult to write a proper application to *support* a "means"-defined element because the specification must correlate the "means"-defined element as to its stated function with the structure or material disclosed in the specification. Thus, under 35 USC § 112(f), "[a]n element in a claim for a combination may be expressed as a means … for performing a *specified function* without the recital of structure [or] material … in support thereof…."

Patentees seeking to enforce claims with "means"-defined elements have had a very difficult track record at the Federal Circuit. *See Blackboard, Inc. v. Desire2Learn, Inc*., 574 F.3d 1371 (Fed. Cir., 2009)(discussing *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology,* 521 F.3d 1328 (Fed.Cir. 2008); *Net MoneyIN, Inc. v. VeriSign, Inc.,* 545 F.3d 1359 (Fed. Cir. 2008); *Finisar Corp. v. DirecTV Group, Inc*., 523 F.3d 1323 (Fed. Cir. 2008); *Medical Instrumentation & Diagnostics Corp. v. Elekta AB,* 344 F.3d 1205 (Fed.Cir.2003); *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374 (Fed.Cir. 1999)).

As explained by Circuit Judge O'Malley in *Noah Sys., Inc. v. Intuit Inc.,* 675 F.3d 1302 (Fed. Cir. 2012), a software patent may face an indefiniteness challenge either where there is no algorithm disclosed in the patent or where the patent challenger questions the sufficiency of the disclosure. Thus:

> [Federal Circuit] case law regarding special purpose computer-implemented means-plus-functions claims is divided into two distinct groups: First, cases in which the specification discloses no algorithm; and second, cases in which the specification does disclose an algorithm but a defendant contends that disclosure is inadequate. *Compare Blackboard, Inc. v. Desire2Learn Inc.*, 574 F.3d 1371, 1383–85 (Fed.Cir.2009) (no algorithm) with *WMS Gaming*[, *Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed.Cir.1999)] (algorithm). This distinction is important because we have clarified that, while "[i]t is certainly true that the sufficiency of the disclosure of algorithmic structure must be judged in light of what one of ordinary skill in the art would understand the disclosure to impart," in a situation in which the specification discloses no algorithm, "[t]hat principle ... has no application...." *Aristocrat* [*Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1337 (Fed.Cir.2008)]; *see Atmel* [*Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed.Cir.1999)] ("Fulfillment of the § 112, ¶ 6 tradeoff cannot be satisfied when there is a total omission of structure. There must be structure in the specification. This conclusion is not inconsistent with the fact that the knowledge of one skilled in the particular art may be used to understand what structure(s) the specification discloses ... because such resources may only be employed in relation

to structure that is disclosed in the specification."); *see also Default Proof Credit Card Sys.*[*, Inc. v. Home Depot U.S.A., Inc.,* 412 F.3d 1291, 1301 (Fed.Cir.2005)] ("The inquiry under § 112, ¶ 2 ... asks first 'whether structure *is* described in [the] specification, and, if so, whether one skilled in the art would identify the structure from that description.' " (quoting *Atmel Corp. v. Info. Storage Devices, Inc.,* 198 F.3d 1374, 1381 (Fed.Cir.1999))]. Where no structure appears, the question "is not whether the algorithm that was disclosed was described with sufficient specificity, but whether an algorithm was disclosed at all." *Aristocrat* [*Techs. Austl. Pty Ltd. v. Int'l Game Tech.,* 521 F.3d 1328, 1337 (Fed.Cir.2008)]. When the specification discloses some algorithm, on the other hand, the question is whether the disclosed algorithm, from the viewpoint of a person of ordinary skill, is sufficient to define the structure and make the bounds of the claim understandable. *AllVoice Computing* [*PLC v. Nuance Commc'ns., Inc.,* 504 F.3d 1236, 1245 (Fed.Cir.2007)].

Noah v. Intuit, 675 F. 3d at 1312.

§ 18[d][2] Sec. 112(f) Disclosure is not an Enablement Issue

"Means for" terminology is a statutory trigger to invoke the presumption that a functional claim should be interpreted according to 35 USC § 112(f) of the *Leahy Smith America Invents Act*:

"ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a *means ... for* performing a specified function without the recital of structure [or] material … in support thereof, and such claim shall be construed to cover the corresponding structure [or] material … described in the specification and equivalents thereof."

The argument is sometimes made that where a claim is to a "means"-defined element and that element relates to software, it is unnecessary to disclose software that can be used to practice the invention because, once the invention is disclosed (minus a supporting algorithm) anyone skilled in the art would be able to create an operative algorithm. In other words, it would be obvious how to construct an operative algorithm.

This argument totally misses the point that the algorithm is the "corresponding structure" in the specification in support of the "means"-defined definition. Thus, the question is one of *disclosure* of the "corresponding structure" within the meaning of 35 USC § 112(f) that is at issue. So, it may well be that it is obvious how to create an operative algorithm, but that is not the point.

§18[d][3] "Katz Exception" with No Need for Algorithm Disclosure

Exceptionally, a means-plus-function claim *without* supporting algorithm disclosure is acceptable where *any* general purpose computer may be used in the claimed invention. This is cited as the "Katz Exception" in *Eon Corp. IP Holdings LLC v. AT&T Mobility LLC* , __ F.3d __, __ (Fed. Cir. 2015)(Prost, J.)(citing *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303 (Fed. Cir. 2011)). Thus:

"[*Blackboard, Inc. v. Desire2Learn, Inc*., 574 F.3d 1371, 1385 (Fed. Cir. 2009); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1367 (Fed. Cir. 2008); *Finisar Corp. v. DirecTV Grp*., 523 F.3d 1323, 1340–41 (Fed. Cir. 2008); and *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.,* 521 F.3d 1328, 1338 (Fed. Cir. 2008)] involved specific functions that would need to be implemented by programming a general purpose computer to convert it into a special purpose computer capable of performing those specified functions. See, e.g., *Aristocrat*, 521 F.3d at 1333–34; *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1253 (Fed. Cir. 2005); *WMS Gaming*[, *Inc. v. Int'l Game Tech.,* 184 F.3d 1339, 1349 (Fed. Cir. 1999)]. By contrast, … Katz has not claimed a specific function performed by a special purpose computer, but has simply recited the claimed functions of 'processing,' 'receiving," and 'storing.' Absent a possible narrower construction of the terms 'processing," 'receiving,' and 'storing,' … those functions can be achieved by any general purpose computer without special programming."

Katz, 639 F.3d at 1316.

§ 18[e] Separate Views of the *En Banc* Court in *Williamson*

§18[e][1] "Sidestep[ping] Fundamental Issues"

One of the members of the en banc *Williamson* court continued in his tradition of seeking the exploration of major issues beyond the immediate question before the Court. *Williamson v. Citrix Online, LLC.*, __ F.3d at ___ (Fed. Cir. 2015)(en banc in relevant part)(Reyna, J., concurring-in-part, dissenting-in-part, and additional views). On the one hand he *concurs with the result* where the majority overrules case law, inter alia, *Inventio AG v. ThyssenKrupp Elevator Americas Corp*., 649 F.3d 1350, 1360 (Fed. Cir. 2011), which the dissent characterizes as "describing a 'strong' presumption in favor of § 112, paragraph 6 application where a claim recites 'means.'" But, in the same paragraph this jurist "question[s] whether those statements sidestep underlying fundamental issues involving the development of functional claiming law since 1952 when 35 U.S.C. § 112, paragraph 6[Ed. note] was passed."

While in agreement with the holding overruling case law, the dissent charges that the majority has ignored "fundamental concerns". Thus, the majority opinion "stop[s] short of addressing other equally fundamental concerns about functional claiming." *Id.*

The opinion also takes a unique position never before expressed. The opinion refers to "the fact that [35 USC § 112(f)] uses both terms—'means' and 'step'—[which] would suggest that any presumption should apply to the use of either word. Yet, it is arguably not clear to what extent this court attaches a presumption to the word 'step.'" *Id.*

[Ed. note] The 1952 Patent Act did not have six paragraphs. The "means" provision was 35 USC § 112 ¶ 3 at the time of enactment and stayed that way until a statutory amendment in 1965.

Indeed, there is a paucity of any case law on point as to "step" claims. *Query*: What major precedent exists as to "step" claims for *any* point of law? How often has an issue unique to a "step" claim been decided by the Federal Circuit?

§18[e][2] Unique Concerns over the Means Presumption

One of the eleven members of the *en banc* Court issued a dissent that speaks for itself:

"The court now overrules dozens of cases referring to a 'strong presumption' of means-plus-function usage, and goes to the opposite extreme, holding that this court will create such usage from '[g]eneric terms such as 'mechanism,' 'element,' 'device,' and other nonce words.' Maj. Op. at 17. In the case before us, the so-called "nonce" word is "module." Thus the court erases the statutory text, and holds that no one will know whether a patentee intended means-plus-function claiming until this court tells us.

* * *

"I urge the court to recognize that it is the applicant's choice during prosecution whether or not to invoke paragraph 6, and the court's job is to hold the patentee to his or her choice. This approach is clear, easy to administer by the USPTO in examination and the courts in litigation, and does no harm, for patent applicants know how to invoke paragraph 6 if they choose."

Williamson v. Citrix Online, LLC., __ F.3d at ___ (Fed. Cir. 2015)(en banc in relevant part)(Newman, J., dissenting).

The answer is that the applicant *can* choose statutory "means" claim interpretation by use of the "means for" terminology *and by reciting structure* in support of the "means for"-defined element.

PART (IV): SPECIFICATION TO SUPPORT THE CLAIMS

§ 19. Simplicity, Key to Supporting the Claimed Invention

The holistic approach to patent drafting is clearly best – or any other route the applicant takes to reach the result of a patent application with a simple presentation of a few claims, few citations of prior art and a non-argumentative exposition of the invention.

There are several matters that may not at first blush be apparent:

§ 19[a] The Production Quota for the Examiner

The Patent Examiner in the first instance needs a certain level of production to maintain his position or be promoted. Beyond that, a *higher* level of production is needed for a cash bonus each year.

If the Examiner to meet his own self-set production goals can allocate, say, ten hours for a first action on the merits, consider two contrasting examples:

> **Situation (I)**: The first application is a holistic application with three prior art references, without argumentation, eight claims (with only "claim 1" in independent form), and a totally "flat" presentation without argumentation.

> **Situation (II)**: The second application has fifty prior art references and fifty claims and an argumentative *Background of the Invention.*

In Situation (I) the Examiner has a very easy search to conduct. Instead of starting from scratch and saving twenty or so prior art references after careful reflection, in this holistic example the Examiner instead has the goal of seeing whether the three prior art references cited by the applicant are indeed the best prior art references. His search thus is focused on *beating* the applicant's search, to see if there is any prior art *closer* than that which the applicant has presented. Already the Examiner has saved a considerable slug of time through the search results provided by the applicant.

The Examiner in Situation (I) now has the task of measuring "claim 1" against the closest prior art, a matter that should be wrapped up in a matter of an hour or so. If the patentability looks close, the Examiner may spend another hour or so searching for a "secondary" (or teaching) reference. If a rejection *is* made for obviousness it will likely be based upon the one most pertinent prior art reference – either alone or in view of one or two "secondary" references.

The Examiner in Situation (I) will also have time to go through the claims with a fine tooth comb and reject any claims under Section 112 with real *or apparent* weaknesses.

In other words, the Examiner in Situation (I) is able to perform a *complete examination on the merits within his allotted time window.*

In terms of nonobviousness issues, the applicant in response to the Situation (I) rejection is now able to see whether an amendment is necessary to the claims to establish nonobviousness or whether evidence should be presented to overcome any rejection. The applicant has the absolute *right* to amend and present evidence at this stage because the application stands rejected *without* a Final Rejection.

In terms of formal issues under Section 112, if the Examiner's position does have merit, the applicant is able to *amend* the claims at this stage to obviate the rejection. (This is far, far better than gaining an allowance with a real defect that can be challenged at the Patent Trial and Appeal Board in a Post Grant Review.) The applicant is also the winner if the Examiner has exposed what is only an *apparent* defect under Section 112: The issue has been exposed in the rejection and now the applicant has the opportunity to clarify *why* the claims pass Section 112 muster, creating a more solid prosecution history for defense of the patent that will be granted.

In Situation (II) it is hardly feasible that the Examiner will be able to accomplish a complete first action on the merits within ten hours. First of all, the search results are hardly helpful: The fifty references cited by the applicant in Situation (II) hardly help to clarify what is the closest prior art. The greater the number of citations by the applicant the less helpful the information is to the Examiner. Instead of using the prior art references in Situation (II) in the manner of the earlier example, here, the Examiner is more likely to start his search from scratch.

Blending in the factor of fifty claims in Situation (II) geometrically complicates the examination to make the Examiner's task far, far more time consuming.

It is also likely that the Examiner will *not* have enough time to go past his primary task of examining claims to see whether they represent a patentable contribution under Section 103. In the end, it is likely that the Examiner will see the futility of his task within his allotted time frame and simply seek to "bury" the application so that it cannot be granted before a Final Rejection – thus requiring

the applicant to file a Request for Continued Examination or to refile the application under Section 120.

A hint that this has been the fate of the applicant will be manifested by a "Combination Rejection" of a set of seemingly close prior art references "A", "B" and "C" together with "teaching" references "D", "E" and "F":

> Claims 1-50 are rejected under 35 USC § 103 a obvious over "A", "B" and "C", each taken alone or in combination with references "D", "E" and "F".

Further evidence that the Examiner has not done a complete first action will be seen through an absence of *real* formal rejections under 35 USC § 112.

The Examiner's "Combination Rejection" has doomed the applicant to never gaining a patent in the current examination. The second action will be a Final Rejection where the issues have hardly been joined. An appeal would be fruitless, thus requiring a Request for Continued Examination or other refiling.

Furthermore, the Examiner will be most reluctant in any event to grant the patent on this record because there will undoubtedly be formal matters amongst the fifty claims that, upon Quality Review after allowance, would ding the Examiner's record and harm his standing in the Office. (Quality Review is avoided simply by *maintaining* the rejection of the application.)

§ 19[b] Supervisory Primary Examiner Intervention

In Situation (I) of the previous section, if the Examiner is at a lower grade level there may be the opportunity for *meaningful* review by the Supervisory Primary Examiner because the case is *simple* and easy to understand.

In Situation (II) the record may become extremely complex. So, while there may be the opportunity for Supervisory Primary Examiner review, in fact the review may be so time consuming and difficult that the default answer will be to sustain the Examiner's rejection.

§ 19[c] Appellate Review at the PTAB

Appeal to the Patent Trial and Appeal Board (PTAB) is much more likely to be successful in Situation (I) than in Situation (II).

A crisp appeal brief focused on one issue in In Situation (I) may very well lead to the allowance of the case *by the Examiners* because the issue is clearly framed and easy to understand.

In Situation (II) it may be very difficult to sort through the complex web of the prosecution history, making reversal at the PTAB unlikely and even more surely leading to the Examiner *maintaining* the rejection and forcing the case to reach the PTAB.

§19[d] Complete Harmony with the Claim Wording

By far the greatest simplification of the drafting from an *affirmative* side is found in a properly drafted *Summary of the Invention.* Simplicity, here, refers to what should be included in the patent application, which is the subject of this section.

Simplicity in patent drafting from a *negative* side refers to what should *not* be included in the patent application, which is the subject of the section which follows this discussion of what *should* be included in the application.

The claim language should be reproduced word for word as the Summary of the Invention. A verb should be added to each claim to make a complete sentence. (Thus, "A product comprising ***" in claim 1 is reworked as "A product *is provided* comprising ***".) *The wording to describe the invention should be identical in both the claims and the Summary.*

The *Manual* in one portion of that document makes it clear that claims lacking support in the specification should be objected to: "The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import…." MPEP **§** 608.01(o), *Basis for Claim Terminology in Description.*

In the *Gardner* case the Commissioner argued that the specification *must* contain a disclosure of the invention of 'claim 1' in the specification: "While an original claim may be considered as a part of the original disclosure, it should not be considered a part of the 'written description'—unless the specification contains

or is amended to contain the subject matter of the original claim." *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973)(quoting argument of the Solicitor).

As explained in *Technology Licensing* "a claim in a later application receives the benefit of the filing date of an earlier application so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, *including the written description requirement*, with respect to that claim." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir. 2008)(citing *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed.Cir.1994)). Thus, "a patent must contain a written description of the claimed invention in 'full, clear, concise, and exact' terms. 35 U.S.C. § 112, ¶ 1. [Where] a patentee seeks the benefit of the filing date of an earlier filed application, compliance with the written description requirement may turn on whether the disclosure of the earlier application provides 'adequate support' for the claims at issue." *Technology Licensing*, 545 F.3d at 1324 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F. 2d 1555, 1560 (Fed.Cir.1991)).

Fortunately, in terms of whether a claim lacking disclosure in the specification passes statutory muster, it is clear that an original claim is a part of the specification as filed so that if the disclosure of the claim is lacking in the body of the specification, it is procedurally possible to amend the Summary of the Invention to include a recitation of the definitions of the original claims.

Unfortunately, if the original claims (or the remainder of the original specification) lack *definitions* of the terms of the claims, then the applicant may be out of luck to cure a deficiency in terms of definitions of the invention.

As to the right to *amend* the specification to include the text from an *original* claim, this is explained by Judge Lourie in *Enzo*, "[t]here is no question that an

original claim is part of the specification. That was the question answered in the affirmative by *In re Gardner*, 480 F.2d 879 (CCPA1973), in which the CCPA found compliance with the written description requirement over the objection of the PTO Commissioner, who argued that an original claim should not be considered part of the written description unless the specification was amended to contain the subject matter of the original claim." *Enzo Biochem, Inc. v. Gen-Probe Inc*., 323 F.3d 956, 972 (Fed. Cir., 2002)(on pet. for reh'g)(Lourie, J.). This statement echoes what Judge Lane had said shortly after the *Gardner* case:

"Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied." *In re Smith*, 481 F.2d 910, 914 (CCPA 1973)(Lane, J.)(citing *In re Gardner*, 475 F.2d 1389 (CCPA 1973), *supplemental opinion*, 480 F.2d 879 (CCPA 1973); *In re DiLeone*, 436 F.2d 1404 (CCPA 1971)). *See also In re Koller*, 613 F.2d 819, 823 (CCPA 1980) ("[O]riginal claims constitute their own description.").

§ 19[e] **Exemplification of Alternate Embodiments**

As noted in this section, it is important to identify alternate embodiments for an element of the claim where the examples only show one particular embodiment. Additionally, provision of plural working examples may be important in an unpredictable technology. *See* § 527, *Plural Embodiments to Show "Possession" of the Invention.*

§ 19[e][1] Establishing that the Inventor Possessed the Genus

Features recited in the claims – whether or not at the point of novelty – should have support from plural features. This can conveniently be accomplished after the first appearance of a term in the *Summary of the Invention.* For example, if the claim calls for a "signal" and the only exemplification in the specification is of a horn, it is useful to include a statement along the following lines:

"As the "signal" which is part of the claimed invention may be mentioned a horn, a strobe light or a vibrator."

Particularly if one feature of the claimed invention is supported by only one example, case law at the Federal Circuit has treated patentees unkindly in two ways.

First, under *LizardTech* if there is only one feature disclosed for an element in a claimed combination one may face a challenge under what is today 35 USC § 112(a): "In order to meet the written description requirement of 35 U.S.C. § 112, the specification 'must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed.'" *Honeywell Intern., Inc. v. United States*, 596 F.3d 800, 816 (Fed. Cir. 2010)(Mayer, J., dissenting in part)(*quoting LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed.Cir.2005).

Second, there is a line of case law that – rightly or wrongly – will read the narrowly *supported* feature as a limitation to the claims:

"To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. See *Spectra-Physics, Inc. v. Coherent, Inc*., 827 F.2d 1524, 1533 (Fed.Cir.1987). One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. See *SciMed Life* [*Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed.Cir.2001)]. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent. See *Snow v. Lake Shore & M.S. Ry. Co.*, 121 U.S. 617, 630 (1887) (it was clear from the specification that there was 'nothing in the context to indicate that the patentee contemplated any alternative" embodiment to the one presented).'" *Phillips v. AWH Corp*., 415 F.3d 1303, 1323 (Fed. Cir. 2005)(en banc)(Bryson, J.).

In *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1344 (Fed.Cir.2001)(Bryson, J.), the author of *Phillips* provides a further explanation of the role of a narrowly drafted specification:

"Citing *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998), and *Johnson Worldwide Assocs. v. Zebco Corp*., 175 F.3d 985, 989-90 (Fed. Cir. 1999), SciMed argues that the only way in which statements in the written description can restrict the scope of a claim is by setting forth a specific, narrowing definition for a particular claim term. SciMed's characterization of the role of the written description is too narrow. While it is true, of course, that 'the claims define the scope of the right to exclude' and that 'the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim,' *Renishaw PLC*, 158 F.3d at 1248, the written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format. See, e. g., *Phonometrics, Inc. v. Northern Telecom Inc.*, 133 F.3d 1459, 1466 (Fed. Cir. 1998); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc*., 93 F.3d 766, 769-70 (Fed. Cir. 1996); *Carroll Touch, Inc. v. Electro Mech. Sys., Inc*., 15 F.3d 1573, 1577-78 (Fed. Cir. 1993); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1566, 1567 (Fed. Cir. 1992)."

SciMed Life, 242 F.3d at 1344.

Chief Judge Prost has more recently explained that even in the face of a definition the specification, if not carefully drafted, can produce a narrower interpretation than may have been the intention of the applicant. In *SkinMedica* the author of *SciMed* further elaborated:

Disclaiming the ordinary meaning of a claim term—and thus, in effect, redefining it—can be affected through "repeated and definitive remarks in the written description." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed.Cir.2008) (citing *Watts v. XL Sys.*, 232 F.3d 877, 882 (Fed.Cir.2000)); see *SafeTCare Mfg., Inc. v. Tele–Made, Inc.*, 497 F.3d 1262, 1270 (Fed.Cir.2007) (finding disclaimer of "pulling force" where "the written description repeatedly emphasized that the motor of the patented invention applied a pushing force"); *SciMed*, 242 F.3d at 1344 ("[T]he written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format."); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed.Cir.2001) ("[A] claim term may be clearly redefined without an explicit statement of redefinition.... In other words, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." (citations omitted) (internal quotation marks omitted)); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996) ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.").

We do, though, "recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Phillips*, 415 F.3d at 1323. However, we can rely on the specification "to understand what the patentee has claimed and disclaimed." *SafeTCare Mfg.*, 497 F.3d at 1270.

Skinmedica, Inc. v. Histogen Inc., 727 F.3d 1187, 1196 (Fed. Cir. 2013)

§ 19[e][2] The Inventor "Actually Invented" the Genus

It is helpful to provide alternative embodiments in support of an element of a claim, particularly where the actual examples are only focused on one particular embodiment. Without a disclosure of alternate embodiments, some members of the Federal Circuit view the subject matter as "actually invented" to be with the one disclosed embodiment.

Support for the view that the specification should be used to interpret the claims where there is a paucity of alternate embodiments, the *en banc* Court in the *Phillips* case stated that:

"In light of the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims. See *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed.Cir. 2003) ('A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.') (citations omitted)." *Phillips v. AWH Corp*., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc)(Bryson, J.)

Thus, "[u]ltimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips,*, 415 F.3d at 1316 (quoting with approval *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998)). *See also Superguide Corp. v. DirecTV Enterprises, Inc*., 358 F.3d 870, 896 (Fed. Cir., 2004)(Michel, J., concurring)("The majority's claim constructions expand the scope of the [ ] patent far beyond what the named inventors say they *actually invented* in their application, and what it describes and enables.")(emphasis added).

As explained in *Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013)(Schall, J.):

"To satisfy the written description requirement, 'the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent.' *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). Accordingly, claims added during prosecution must find support sufficient to satisfy § 112 in the written description of the original priority application. See, e.g., *Anascape, Ltd. v. Nintendo of Am., Inc*., 601 F.3d 1333, 1335 (Fed. Cir. 2010). Assessing 'possession as shown in the disclosure' requires 'an objective inquiry into the four corners of the specification.' Ariad, 598 F.3d at 1351. Ultimately, 'the specification must describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed.' Id. A 'mere wish or plan' for obtaining the claimed invention does not satisfy the written description requirement. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997)."

See also § 7[f], *Generic Support for an "Unpredictable" Ariad Invention* (citing *Allergan, Inc. v. Sandoz Inc.*, __ F.3d __ (Fed. Cir. 2015)(Lourie, J.); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002)

To be sure, the issue is clouded with uncertainty at the Federal Circuit as seen from several dissents including *Retractable Technologies Inc. v. Becton Dickinson*, 659 F.3d 1369 (Fed. Cir., 2011)(den. reh'g en banc), and *Free Motion Fitness, Inc. v. Cybex Intern., Inc.*, 423 F.3d 1343 (Fed. Cir., 2005).

As explained in *Retractable Technologies:*

"The error [at the panel level] is the majority's attempt to rewrite the claims to better conform to what it discerns is the 'invention' of the patent instead of construing the language of the claim. Indeed, the majority candidly explained that its construction… 'is required to tether the claims to what the specifications indicate the inventor *actually invented*.' [*Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed.Cir.2011)]. The majority reaches this conclusion based on the examples disclosed in the specification that have a 'one piece' body, an indication in the specification that the invention 'features a one piece' body, and the disclosure that the syringe 'can be molded as one piece.' Id. Yet none of these statements in the specification suggest that 'body' actually means 'one-piece body'; to the contrary, the use of the modifier 'one piece' strongly implies that the term 'body' does not inherently mean objects made solely of one piece. *Phillips*[*v. AWH Corp*., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc)(Bryson, J.)]. Regardless of what 'the inventor *actually invented*,' it is clear that the only construction of the term 'body' that comports with the patent as a whole, as well as the plain meaning of the term, includes both single and multi-piece bodies.

Retractable Technologies, 659 F.3d at 1372Moore, J., joined by Rader, C.J., dissenting from den. reh'g en banc).

In *Free Motion* the dissent stated:

"The majority's approach… does not attempt to determine what the inventor *actually invented*, but rather takes the broadest available abstract meaning of a claim term that is not explicitly rejected by the specification. This approach allows the claim scope to extend beyond what the inventor's written description and claims show to be his actual invention. [The] inventor came up with a specific structure that he described and claimed. By deviating from the meaning of 'adjacent' that is most closely aligned with all the examples in the specification, the majority awards him more than he *actually invented* and claimed."

Free Motion, 423 F.3d at 1355 (Prost, J., dissenting)(emphasis added).

§ 19[f] Definitions at the Point of Novelty

In *addition* to exemplification of terms to support the claims, a *definition* of terms at the point of novelty will provide a clear line of demarcation of the claimed subject matter from the prior art. This will help avoid an unnecessarily broad interpretation under the "broadest reasonable interpretation" rule used at the Patent Trial and Appeal Board for its post-grant proceedings.

"[P]atentees can act as their own lexicographers if they ''clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning.'" *Vasudevan Software, Inc. v. Microstrategy, Inc.*, __ F.3d __, ___ (Fed. Cir., 2015)(Linn, J.)(quoting *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012), quoting *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

Words that need a definition should be placed in parenthesis and defined in the text immediately following the repetition of the wording of the claims.

The need for definitions of terms is seen from the statement of Circuit Judge Newman:

Words are symbols, linguistic embodiments of information sought to be communicated, and, as such, can be imperfect at representing their subject. The Supreme Court recently observed this challenge to patent claim interpretation, stating in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128-29

(2014), that "the definiteness requirement must take into account the inherent limitations of language," and that clarity is required although "recognizing that absolute precision is unattainable." When the disputed words describe technology, the terse usage of patent claims often requires "construction" in order to define and establish the legal right. Judicial "construction" of patent claims aims to state the boundaries of the patented subject matter, not to change that which was invented.

Fenner Investments, Ltd. v. Cellco Partnership, __ F.3d __ (Fed. Cir. 2015)(Newman, J.)

While the best way to provide an express definition of a term is to place that term in quotation marks, in the context of a definitional interpretation in the prosecution history, the court has approved the use of the phrase "refers to" as a definitional term: "An applicant's use of the phrase 'refers to' generally indicates an intention to define a term." *Vasudevan Software, Inc. v. Microstrategy, Inc.*, __ F.3d __, ___ (Fed. Cir., 2015)(Linn, J.)(citing *In re Imes*, 778 F.3d 1250, 1252-53 (Fed. Cir. 2015); *Microsoft Corp. v. Int'l Trade Comm'n*, 731 F.3d 1354, 1360 (Fed. Cir. 2013); *Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1054 (Fed. Cir. 2009)).

§ 19[f][1] Claim Boundaries Determined with "Reasonable Certainty"

For the first time in more than seventy years the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), reviewed the issue of claiming definiteness under what is now 35 USC § 112(b). Until the Federal Circuit issues either an *en banc* decision or a set of consistent panel opinions over the coming years, the law in this area must be considered fluid.

§ 19[f][2] Obfuscation to Deny "Reasonable Certainty"

To the extent that a patent applicant files, say, fifty claims with ambiguities created by internal inconsistences or where the applicant in prosecution explains support for claims based upon the wrong section of the patent application, do such *unnecessary* ambiguities mean that the applicant has failed to define the invention with "reasonable certainty"?

§ 19[g] "Best Mode Contemplated" Should be Disclosed

The "best mode contemplated" requirement of the patent law *remains* as part of the *Leahy Smith America Invents Act. See* § 19[g][1], *"Best Mode Contemplated" Requirement is Maintained.* But, a good faith violation of the best mode requirement is clearly no longer a basis to lose the patent right because a best mode challenge can be raised neither in a District Court patent infringement action, *see* § 19[g][2], *"Best Mode" Violation is not a Defense to Patent Infringement,* nor at the Patent Office in a Post Grant Proceeding, § 19[g][3], *"Best Mode" Violation not Permitted in Post Grant Review*.

Open questions still remain, however, whether an inequitable conduct charge can be successfully raised with deliberate obfuscation of the best mode such as through substitution of a fictitious, inoperative best mode, *see* § 19[g][4], *Deliberate Obfuscation of Best Mode May Lead to Unenforceability.*

A successful inequitable conduct charge under the new law would represent a significant change in the practice. *See* § 19[g][5], *Willful Violation of the Best Mode Requirement: Uncharted Waters.*

To the extent that there *is* a best mode that the patent practitioner *should* know about and *would know* about through the normal course of business, deliberate avoidance of such knowledge may not be sufficient to escape liability. *See* § 19[g][6], Liability for Deliberate Avoidance of Best Mode Knowledge.

The law of best mode has been further liberalized in the Leahy Smith America Invents Act by permitting the applicant to file an application *with* the best mode that claims priority to a provisional application *without* the best mode. *See* § 19[g][7], *Priority to Provisional without Disclosure of the Best Mode*.

Although there is no explicit wording change to 35 USC § 119 insofar as a Paris Convention priority right is concerned, there is a strong argument that if a United States application *discloses* the best mode while the "home country" priority document does not disclose the best mode, priority nevertheless should be granted. *See* § 19[g][8], *Paris Convention Priority where Foreign Parent Lacks the Best Mode.* The applicant may also file a continuation-in-part to add the best mode *without losing a right of priority. See* § 19[g][9], *Continuation-in-Part May Add the Best Mode Contemplated*.

§ 19[g][1] "Best Mode Contemplated" Requirement is Maintained

The Leahy Smith America Invents Act makes a major change in the law by denying a basis for a third party attack against the patentee who has failed to disclose the "best mode contemplated".

Thus, on the one hand, there *remains* a statutory requirement to disclose the "best mode contemplated" by the inventor for carrying out his invention. This is spelled out in 35 USC § 112(a): "The specification *** shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."

The complete text of this section reads:

"*The specification* shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and *shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention*."

§ 19[g][2] Violation is not a Direct Defense to Patent Infringement

The denial of a best mode attack in litigation is explicitly stated in 35 USC § 282(b)(3)(A):

"The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: …
Invalidity of the patent or any claim in suit for failure to comply with –
any requirement of section 112 , except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable…."
35 USC § 282(b)(3)(A)

§ 19[g][3] "Best Mode" Violation not Permitted in Post Grant Review

A failure to meet the best mode requirement may not be challenged at the Patent Office in a post grant proceeding under 35 USC § 321(b): "A petitioner in a post-grant review may request to cancel … claims of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)." 35 USC § 321(b).

But, as explained in the previous section, "best mode" is *not* basis for an attack under 35 USC § 282(b).

§ 19[g][4] Deliberate Obfuscation May Lead to Unenforceability

Whether a deliberate obfuscation of the best mode may be attacked on the basis of inequitable conduct is an open question. The classic case where such an attack was successful is *Consolidated Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804 (Fed. Cir. 1990)).

It is well settled that an "intentional concealment of a best mode coupled with disclosure of a false mode of practicing an invention may constitute inequitable conduct rendering a patent unenforceable." *U.S. Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1216 n.8 (Fed. Cir. 1996)(dictum)(citing *Consolidated Aluminum*). But, even under the old law a successful ruling against the patentee on the basis of inequitable conduct keyed to a best mode violation has

not been looked on with favor as seen from *Old Town Canoe Co. v. Confluence Holdings Corp*., 448 F.3d 1309 (Fed. Cir. 2006).

Consolidated Aluminum confirmed a ruling of inequitable conduct where the patentee had *both* concealed the best mode and *fabricated an inoperative* mode that it disclosed in its patent. It was this egregious conduct of *fabrication* of an inoperative embodiment that struck the nerve of the Court.

The Federal Circuit in *Consolidated Aluminum* noted that "the special master found that Consolidated committed inequitable conduct by intentionally withholding the best mode contemplated by the inventors for practicing the invention of [one of the patents] and by disclosing a fictitious, inoperable mode[.]" *Consolidated Aluminum*, 910 F.2d at 807.

The egregious nature of the conduct in *Consolidated Aluminum* is best appreciated by reading the opinion itself:

Consolidated Aluminum Corp. v. Foseco Intern. Ltd.
910 F.2d 804 (Fed. Cir. 1990)

Markey, Circuit Judge.

* * *

OPINION

Inequitable Conduct Renders the '917 Patent Unenforceable

The special master found that Consolidated committed inequitable conduct by intentionally withholding the best mode contemplated by the inventors for practicing the invention of the '917 patent and by disclosing a fictitious, inoperable mode:

"The evidence shows that the best mode known at the time of the filing of the '917 patent was the 'CS1-B' slurry containing aluminum oxide, chromium oxide, kaolin, bentonite, aluminum orthophosphate, and water which is later disclosed and claimed in the '363 patent. Instead of disclosing the actual slurry used to make the filters tested and reported in the patent, a fictitious inoperable slurry was disclosed as Example 1 that omitted key ingredients such as the thixotropic clays kaolin, bentonite, and the aluminum orthophosphate binder necessary to hold the ceramic together. Dr. Pryor [one of the inventors] admitted that the '363 patent represents the undisclosed 'best mode' of the '917 patent. The evidence shows that both Dr. Pryor and Dr. Gray [the other inventor] knew that Example 1 of the '917 patent was inoperative and not the best mode, and that the 'CS1- slurry as disclosed in the '363 patent was the best mode used to make the filters that were actually tested as reported in the '917 patent. The testimony of Dr. Pryor also shows that he knew that the 'CS1-B' slurry was not going to be disclosed in the application because he instructed the patent attorney, Mr. Bachman, to add the sentence at Col. 3, ln. 39-40, 'Additives may be employed in the slurry such as binders.' Inclusion of this sentence would have been unnecessary if the 'CS1-B' slurry which contained a binder was going to be disclosed. Thus, the evidence supports the inference that the withholding of the best mode and inclusion of an unworkable fictitious slurry was intentional. Had the examiner known that the best mode had been withheld, the '917 patent application would not have been allowed to issue under the 35 U.S.C. Sec. 112. Thus, the intentional withholding of the best mode represents inequitable conduct in connection with the prosecution of the '917."

[Special Master's Report,] 10 USPQ2d at 1153.

The special master's conclusions reiterated the intentional withholding of the best mode and disclosure of an inoperable mode.

"In the case of the '917 patent, the inventors possessed a specific slurry, with known ingredients at known proportions. The '917 examples

specify a ceramic slurry, but leave actual constituents unnamed and state false proportions for the named constituents. The slurry specified was never used and is inoperable. The ceramic foam reported in the specification examples was made with the undisclosed slurry. Under these circumstances, the quality of the '917 patent disclosure is so poor as to effectively result in concealment. This concealment was not accidental, but was intentional."

Id. at 1167.

The district court agreed with the master's finding that Consolidated not only failed to disclose the best mode in the '917 patent but disclosed a fictitious and inoperable mode, rejected Consolidated's argument that failure to disclose the best mode cannot constitute inequitable conduct, [5] and agreed with the master that Consolidated had engaged in inequitable conduct:

"Because disclosure of the best mode is statutorily required, see 35 U.S.C. Sec. 112, failure to disclose the best mode is inherently material and, we believe, reaches the minimum level of materiality necessary for a finding of inequitable conduct. See *J.P. Stevens [& Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed.Cir.1984)]. On the other hand, sin ce the failure to disclose the best mode is not excused even if unintentional, *Spectra-Physics* [*Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed.Cir. 1987)], but inequitable conduct requires a 'threshold' level of intent, *J.P. Stevens*, 747 F.2d at 1560, the failure to disclose the best mode will not constitute inequitable conduct in every case.

* * * * * *

"Consolidated's concealment was obviously intentional. An inoperable slurry was listed on the patent application although a cited example had been produced with the operable concealed slurry. Moreover, false proportions were listed for slurry constituents and an intentionally vague statement was made on the application."

716 F.Supp. at 326.

Consolidated argues that [it had no] "intent to deceive" and [that the Distrit Court] ignored evidence of subjective good faith.

In so arguing, Consolidated apparently misunderstands our statement in *Kingsdown Medical Consultants Ltd. v. Hollister Inc*., 863 F.2d 867, 876 (Fed.Cir.1988) (in banc), that:

"a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."

Kingsdown stands for the proposition that courts must view the involved conduct "in light of all the evidence" and must then determine whether that conduct in its totality manifests a sufficiently culpable state of mind to warrant a determination that it was inequitable. Here the district court properly made that determination in light of Consolidated's intentional concealment of the CS1-B slurry and disclosure of a fictitious, inoperable slurry. Consolidated does not tell us, nor can we discern, why a finding of intentional concealment under the mask of fictitious mode is not the equal of a finding of intent to deceive. The district court need not have expressed its determination in the particular phrase "intent to deceive". See *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1573 (Fed.Cir.1988) ("A district court need follow no prescribed grammatical formulation in expressing its findings and conclusions."). Consolidated's sole basis for arguing "good faith" lies in its assertion that the CS1-B slurry was invented by Yarwood, Dore and Preuss and was not disclosed because Consolidated properly wished to limit the application for the '917 patent to the invention of the named inventors, Pryor and Gray. That argument must fail, for it ignores the intentional disclosure of a fictitious, inoperable slurry.

The district court did not abuse its discretion in holding the '917 patent unenforceable for inequitable conduct.

Consolidated Aluminum represents a rare and unusual case. For example, note the unsuccessful attempt to attack the patent in a best mode/inequitable conduct attack in *Old Town Canoe*, 448 F.3d at 1321-22:

[The patent challenger] argues that inequitable conduct could [be] based on [the patentee]'s failure to disclose best mode. See *Consol. Aluminum Corp. v. Foseco Int'l, Ltd.*, 910 F.2d 804, 809 (Fed.Cir.1990) (finding inequitable conduct due to intentional concealment of the best mode coupled with disclosure of a false mode of practicing an invention). [The patent challenger] argues that *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959), and *Cabinet Vision v. Cabnetware*, 129 F.3d 595 (Fed.Cir.1997), preclude a trial judge from conducting a bench trial on the equitable issue of unenforceability where that trial would resolve issues that are common to invalidity issues subject to jury resolution. [The patent challenger] overlooks our precedent, which explains that inequitable conduct and invalidity "are distinct and without commonality either as claims or in a relation to the underlying fact issues." *Gardco Mfg., Inc. v. Herst Lighting Co*., 820 F.2d 1209, 1213 (Fed.Cir. 1987). Because the issues of invalidity and unenforceability are distinct in this case, we must address whether the district court abused its discretion in finding the absence of clear and convincing evidence to support [the patent challenger] 's argument for inequitable conduct based on the failure to disclose the 500 RPF canoes or the best mode. See *Kingsdown Med. Consultants Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed.Cir. 1988) (en banc)[.]

Establishing inequitable conduct requires proof by clear and convincing evidence that the misrepresentation made to the PTO was material, and that the patentee acted with intent to deceive the PTO. Id. at 872. Because it is an equitable issue, the ultimate determination of inequitable conduct is committed to the discretion of the trial court. Id. at 876.

As to materiality, there is some evidence that the 500 RPF canoes were material based on their alleged manufacture under the patented method. Concerning best mode, we have held that, "[b]ecause disclosure of the best mode is statutorily required, see 35 U.S.C. § 112, failure to disclose the best mode is inherently material and, we believe, reaches the minimum level of materiality necessary for a finding of inequitab\le conduct." *Consol. Aluminum*, 910 F.2d at

808 (citing *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc*., 747 F.2d 1553, 1559 (Fed.Cir.1984)). The record evidence supporting a failure to disclose best mode may be relevant to a determination of materiality.

Even if materiality is shown, however, [the patent challenger] points to no evidence of intent to deceive the PTO. "[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1351 (Fed.Cir. 2002) (quotation and citation omitted). Furthermore, in *Consolidated Aluminum*, 910 F.2d at 808, we stated that "since the failure to disclose the best mode is not excused even if unintentional, but inequitable conduct requires a `threshold' level of intent, the failure to disclose the best mode will not constitute inequitable conduct in every case." (citations omitted). Confluence does little more than urge this court to draw an inference of intent to deceive, arguing that the applicant or his attorney knew, or should have known that withheld information would be material. Confluence's general argument on this record is not sufficient to enable us to conclude that the district court abused its discretion in finding no inequitable conduct. The district court's JMOL of no inequitable conduct is, thus, affirmed.

§ 19[g][5] Willful Violation, Uncharted Waters

It is a question of first impression for a test case to answer the question whether concealment of the best mode may represent inequitable conduct of a sufficiently egregious nature to warrant rendering a patent unenforceable. While the "best mode contemplated" requirement remains in the law, given that there is no punishment for violation of this requirement, it is difficult to predict that a court would reach a conclusion of inequitable conduct for violation of the best mode requirement. But, if a first test case has egregious facts involving creation of fictitious data as in the previously discussed *Consolidated Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804 (Fed. Cir. 1990)), this would tilt the playing field in the direction of the patent challenger.

§ 19[g][6] Liability for Deliberate Avoidance of Best Mode Knowledge

If the patentee does not *actually* know of a best mode but *deliberately avoids* learning knowledge of the best mode under some circumstances that might be equated with actual knowledge.

Thus, in some instances the patentee may not have *actual* knowledge that there is a violation of the best mode requirement, but if the patentee *deliberately avoids* knowledge of a violation he may be "willfully blind" of such knowledge and then may be under the same standard as if he had actual knowledge. This is explained in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011):

The doctrine of willful blindness is well established in criminal law. Many criminal statutes require proof that a defendant acted knowingly or willfully, and courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances. The traditional rationale for this doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge. Edwards, *The Criminal Degrees of Knowledge*, 17 Mod. L. Rev. 294, 302 (1954) (hereinafter Edwards) (observing on the basis of English authorities that "up to the present day, no real doubt has been cast on the proposition that [willful blindness] is as culpable as actual knowledge"). It is also said that persons who know enough to blind themselves to direct proof of critical facts in effect have actual knowledge of those facts. See *United States v. Jewell*, 532 F. 2d 697, 700 (9th Cir. 1976) (en banc).

This Court's opinion more than a century ago in *Spurr v. United States*, 174 U. S. 728 (1899), while not using the term "willful blindness," endorsed a similar concept. The case involved a criminal statute that prohibited a bank officer from "willfully" certifying a check drawn against insufficient funds. We said that a willful violation would occur "if the [bank] officer purposely keeps himself in ignorance of whether the drawer has money in the bank." Id., at 735. Following our decision in Spurr, several federal prosecutions in the first half of the 20th century invoked the doctrine of willful blindness.7 Later, a 1962 proposed draft of the

Model Penal Code, which has since become official, attempted to incorporate the doctrine by defining "knowledge of the existence of a particular fact" to include a situation in which "a person is aware of a high probability of [the fact's] existence, unless he actually believes that it does not exist." ALI, Model Penal Code §2.02(7) (Proposed Official Draft 1962). Our Court has used the Code's definition as a guide in analyzing whether certain statutory presumptions of knowledge comported with due process. See *Turner v. United States*, 396 U. S. 398, 416-17 (1970); *Leary v. United States*, 395 U. S. 6, 46-47, and n. 93 (1969). And every Court of Appeals—with the possible exception of the District of Columbia Circuit… has fully embraced willful blindness, applying the doctrine to a wide range of criminal statutes.

Given the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U. S. C. §271(b).

§ 19[g][7] Priority to Provisional that Lacks Disclosure of the Best Mode

If the first filing is a provisional application *without* disclosure of the best mode contemplated, a regular application that includes the best mode is entitled to rely upon the filing date of the provisional.

If the inventor has failed to meet the best mode requirement either in a priority application under the Paris Convention or a regular application the defect can be cured by *adding* the best mode to a new application claiming priority to the defective application *without losing the priority of the earlier application.* For a foreign priority application that fails to disclose the best mode contemplated, it is explicitly provided in the statute that the best mode can be added *without* loss of priority:

Priority may be based upon a provisional application that does not disclose the best mode contemplated:

"An application for patent filed under section 111(a)… for an invention disclosed in the manner provided by section 112(a) (*other than the requirement to disclose the best mode*) in a provisional application filed under section 111(b) …shall have the same effect… as though filed on the date of the provisional application….
35 USC § 119(e)(1)(emphasis added).

§ 19[g][8] Paris Convention Priority where Earlier Case Lacks the Best Mode

Paris Convention priority requires compliance with 35 USC § 119(a) that states that the priority standard to obtain benefit of a foreign priority filing date is the same as for benefit of a domestic priority situation:

"An application for patent for an invention filed in this country by any person who has…previously regularly filed an application for a patent for the same invention in a foreign country …shall have *the same effect as the same application would have if filed in this country* on the date on which the application for patent for the same invention was first filed in such foreign country…."
35 USC § 119(a)(emphasis added).

So far there has been no test case to confirm that full priority will be granted based upon a foreign application that fails to disclose the "best mode contemplated".

However, a ruling that priority *should* be granted would be consistent with the case law interpretation of "same effect" in the cases establishing a judicial basis to require a disclosure in a foreign priority application having the same standard as an American priority application. *See Kawai v. Metlesics*, 480 F.2d 880, 889 (CCPA 1973)("[T]he the purpose of the Paris Convention was to have an application made in a foreign country treated as the equivalent of a domestic filing. We believe that equivalent treatment is accorded when the foreign application is weighed under the first paragraph of section 112 in the same manner as would a United States application under section 120."); *see also In re Gosteli*, 872 F.2d 1008, 1011 (Fed. Cir. 1989)("Section 119 provides that a foreign application 'shall have the same effect' as if it had been filed in the United States. 35 U.S.C. § 119. Accordingly, if the effective filing date of what is claimed in a United States application is at issue, to preserve symmetry of treatment between sections 120 and 119, the foreign priority application must be examined to ascertain if it supports, within the meaning of section 112, ¶ 1, what is claimed in the United States application.")

§ 19[g][9] Continuation-in-Part May Add the Best Mode Contemplated

If the original United States application meets the disclosure requirements of enablement under 35 USC § 112(a) but fails to disclose the "best mode contemplated" this defect can be cured by filing a continuation-in-part *adding* the best mode contemplated as part of the original disclosure of the continuation-in-part application. The patent applicant gains a priority right to the parent filing date *even though* the parent was defective as to the best mode requirement.

This scenario is specifically provided for in the patent law: "An application for patent for an invention disclosed in the manner provided by section 112(a) (*other than the requirement to disclose the best mode*) in an application previously filed in the United States… shall have the same effect … as though filed on the date of the prior application…."35 USC § 120, first sentence; emphasis added.

♦ ♦ ♦ ♦ ♦

§20. Definitions to Complement the Claims

§ 20[a] Definitions *always* Belong in the *Summary of the Invention*

By far the greatest simplification of the drafting from an *affirmative* side is found in a properly drafted *Summary of the Invention.*

§ 20[b] The *Summary* Should Mirror the Language of "Claim 1"

The claim language should be reproduced word for word as the Summary of the Invention. A verb should be added to each claim to make a complete sentence. (Thus, "A product comprising ***" in claim 1 is reworked as "A product *is provided* comprising ***".) *The wording to describe the invention should be identical in both the claims and the Summary.*

The *Manual* in one portion of that document makes it clear that claims lacking support in the specification should be objected to: "The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import…." MPEP **§** 608.01(o), *Basis for Claim Terminology in Description.*

In the *Gardner* case the Commissioner argued that the specification *must* contain a disclosure of the invention of 'claim 1' in the specification: "While an original claim may be considered as a part of the original disclosure, it should not be considered a part of the 'written description'—unless the specification contains or is amended to contain the subject matter of the original claim." *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973)(quoting argument of the Solicitor).

As explained in *Technology Licensing* "a claim in a later application receives the benefit of the filing date of an earlier application so long as the disclosure in the earlier application meets the requirements of 35 U.S.C. § 112, ¶ 1, *including the written description requirement*, with respect to that claim." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326 (Fed. Cir. 2008)(citing *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed.Cir.1994)). Thus, "a patent must contain a written description of the claimed invention in 'full, clear, concise, and exact' terms. 35 U.S.C. § 112, ¶ 1. [Where] a patentee seeks the benefit of the filing date of an earlier filed application, compliance with the written description requirement may turn on whether the disclosure of the earlier application provides 'adequate support' for the claims at issue." *Technology Licensing*, 545 F.3d at 1324 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F. 2d 1555, 1560 (Fed.Cir.1991)).

Fortunately, in terms of whether a claim lacking disclosure in the specification passes statutory muster, it is clear that an original claim is a part of the specification as filed so that if the disclosure of the claim is lacking in the body of the specification, it is procedurally possible to amend the Summary of the Invention to include a recitation of the definitions of the original claims.

Unfortunately, if the original claims (or the remainder of the original specification) lack *definitions* of the terms of the claims, then the applicant may be out of luck to cure a deficiency in terms of definitions of the invention.

As to the right to *amend* the specification to include the text from an *original* claim, this is explained by Judge Lourie in *Enzo*, "[t]here is no question that an original claim is part of the specification. That was the question answered in the affirmative by *In re Gardner*, 480 F.2d 879 (CCPA1973), in which the CCPA

found compliance with the written description requirement over the objection of the PTO Commissioner, who argued that an original claim should not be considered part of the written description unless the specification was amended to contain the subject matter of the original claim." *Enzo Biochem, Inc. v. Gen-Probe Inc*., 323 F.3d 956, 972 (Fed. Cir., 2002)(on pet. for reh'g)(Lourie, J.). This statement echoes what Judge Lane had said shortly after the *Gardner* case:

"Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied." *In re Smith*, 481 F.2d 910, 914 (CCPA 1973)(Lane, J.)(citing *In re Gardner*, 475 F.2d 1389 (CCPA 1973), *supplemental opinion*, 480 F.2d 879 (CCPA 1973); *In re DiLeone*, 436 F.2d 1404 (CCPA 1971)). *See also In re Koller*, 613 F.2d 819, 823 (CCPA 1980) ("[O]riginal claims constitute their own description.").

§ 20[c] Definitions at the Point of Novelty

In *addition* to exemplification of terms to support the claims, a *definition* of terms at the point of novelty will provide a clear line of demarcation of the claimed subject matter from the prior art. This will help avoid an unnecessarily broad interpretation under the "broadest reasonable interpretation" rule used at the Patent Trial and Appeal Board for its post-grant proceedings.

"[P]atentees can act as their own lexicographers if they ''clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning.'" *Vasudevan Software, Inc. v. Microstrategy, Inc.*, __ F.3d __, ___ (Fed. Cir., 2015)(Linn, J.)(quoting *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012), quoting *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

Words that need a definition should be placed in parenthesis and defined in the text immediately following the repetition of the wording of the claims.

The need for definitions of terms is seen from the statement of Circuit Judge Newman:

> Words are symbols, linguistic embodiments of information sought to be communicated, and, as such, can be imperfect at representing their subject. The Supreme Court recently observed this challenge to patent claim interpretation, stating in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128-29 (2014), that "the definiteness requirement must take into account the inherent limitations of language," and that clarity is required although "recognizing that absolute precision is unattainable." When the disputed words describe technology, the terse usage of patent claims often requires "construction" in order to define and establish the legal right. Judicial "construction" of patent claims aims to state the boundaries of the patented subject matter, not to change that which was invented.

Fenner Investments, Ltd. v. Cellco Partnership, __ F.3d __ (Fed. Cir. 2015)(Newman, J.)

While the best way to provide an express definition of a term is to place that term in quotation marks, in the context of a definitional interpretation in the prosecution history, the court has approved the use of the phrase "refers to" as a definitional term: "An applicant's use of the phrase 'refers to' generally indicates an intention to define a term." *Vasudevan Software, Inc. v. Microstrategy, Inc.*, __ F.3d __, ___ (Fed. Cir., 2015)(Linn, J.)(citing *In re Imes*, 778 F.3d 1250, 1252-53 (Fed. Cir. 2015); *Microsoft Corp. v. Int'l Trade Comm'n*, 731 F.3d 1354, 1360 (Fed. Cir. 2013); *Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1054 (Fed. Cir. 2009)).

§ 20[d] Claim Boundaries Determined with "Reasonable Certainty"

For the first time in more than seventy years the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), reviewed the issue of claiming definiteness under what is now 35 USC § 112(b). Until the Federal Circuit issues either an *en banc* decision or a set of consistent panel opinions over the coming years, the law in this area must be considered fluid.

§ 20[e] "Reasonable Certainty", Antithesis of an Obscure Definition

To the extent that a patent applicant files, say, fifty claims with ambiguities created by internal inconsistences or where the applicant in prosecution explains support for claims based upon the wrong section of the patent application, do such *unnecessary* ambiguities mean that the applicant has failed to define the invention with "reasonable certainty"?

§ 20[f] Headings to Focus Attention on the *Summary*

Headings that identify the start and finish of the *Summary of the Invention* are useful to direct the Examiner's attention to that portion of the specification that contains essentially all the information needed for his examination. Conveniently, this is consistent with the regulations that govern specification drafting:

"The specification should include the following sections in order:
* * *
(8) Brief summary of the invention.
(9) Brief description of the several views of the drawing.
(10) Detailed description of the invention. * * *"

37 CFR § 1.77(b). It is furthermore a *requirement* that each of the sections be *titled;* the title should under the regulations be centered and capitalized. 37 CFR § 1.77(c)("The text of the specification sections defined in [§ 1.77(b)(1) through § 1.77(b)(12)], if applicable, should be preceded by a section heading in uppercase and without underlining or bold type.")

§ 20[g] Consistent Usage of Terms in the Claims and Specification

A specific term should be used for each element that is recited *verbatim* in the claims and the specification, including both the *Summary of the Invention* and the *Abstract of the Disclosure.* While the term used in the claims will in the first instance define the scope of protection for that element, at the same time the Federal Circuit uses both the *Summary of the Invention* and the *Abstract of the Disclosure* in order to *interpret* the claims. Any deviation where either the *Summary of the Invention* or the *Abstract of the Disclosure* gives a narrow

interpretation to the term may be used to give the claim a narrower definition than if consistent language had been used throughout the specification.

§ 20[h] Coined Term for a Key Element of the Claim

The *Summary of the Invention* should, following the first recitation of a term, particularly for an element at the point of novelty, include a definition of any term that is open to multiple interpretations.

If there are different terms used throughout the specification for an element in the generic claim, then consideration should be given to a generic expression which is a coined term.

If such a coined term is used in the generic claim, then following the first time that term is recited in the *Summary of the Invention* there should be both a specific definition ("By the term 'widget" is meant…") *and* a statement reciting each of the species that is disclosed as an example of that term.

§ 20[i] English that Correctly Expresses the Invention

Language mistakes may be fatal to coverage even where a simple preposition is incorrectly used. In *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed.Cir. 2004), the claimed invention is a bakery process heating dough "to" near incineration temperatures (instead of "at" such temperatures). In *Teknowledge Corp. v. Akamai Technologies, Inc.*, 2004 WL 2042864 (N.D.Cal. 2004)(Illston, J.), the patentee claimed a process with "objects fetched ***from*** [the] clients" where the actual process involves objects fetched ***for*** [the] clients."

Thus, a simple English usage mistake of one word – "from" instead of "for" – led to a nonsensical claim interpretation . Here, the error created a nonsensical meaning for an internet business claim where a part of the process concerns "objects fetched *for* [the] clients"; but, the claim calls for "objects fetched *from* [the] clients".

It is axiomatic that "[c]ourts may not redraft claims to make them operable or to sustain their validity." *In re Papst Licensing Gmbh & Co. Kg Litigation*, 670 F.Supp.2d 16, 29 (D.D.C. 2009)(citing *Chef America*, 358 F.3d at 1374).

United States patent applicants up until the current generation have lived in a dream world that *encouraged* fuzzy claim drafting and *deliberate* ambiguities built into a patent document. Thus, if the boundaries of a patent claim were unclear but the "gist" or "heart" of an invention was copied by an accused infringer, patent applicants relied upon the judicial system to provide leniency to at least compel a settlement.

Often, courts would interpret claims in a way to give them meaning consistent with the specification. Or, even worse, patent applicants could seemingly always rely upon the doctrine of equivalents to get to a jury that would determine infringement: Even if in the end the patentee may lose the case, an accused infringer could not take the business risk of a jury finding him guilty of patent infringement and the shut down of a business line.

The real world of the Federal Circuit today has taken the view that ambiguities shall be resolved *against* the patent owner. Perhaps the best example of the get tough attitude of the mainstream Federal Circuit is in the case of the use of the wrong two letter preposition – "to" instead of "at":

In *Chef America* this led to the entirely nonsensical interpretation that made the patent entirely worthless: The *specification* disclosed a baking process that included a step of heating dough *at* a temperature of up to 850 F. for a period of at little as 10 seconds to set the batter. But, the *claim* instead stated a limitation of "heating the ***dough ***to*** a temperature in the range of about 400 F. to 850 F. for a period of time ranging from about 10 seconds to 5 minutes" for the purpose of setting the batter. Obviously, the examples did not disclose creating a dough product at 850 degrees – a temperature so high that a self-cleaning oven (that *incinerates* residue in an oven) is automatically locked at such a high temperature to safeguard the kitchen user; the temperature would transform any bakery product into a charcoal-like product. Yet, the claim called for heating ***to*** a temperature of 800 degrees, a totally nonsensical result.

In *Teknowledge v. Akamai* a simple English usage mistake of one word – "from" instead of "for" – led to a nonsensical claim interpretation . Here, the error created a nonsensical meaning for an internet business claim where a part of the process concerns "objects fetched *for* [the] clients"; but, the claim calls for "objects fetched *from* [the] clients". Finding this nonsensical claim construction not infringed – and the claim itself fatally indefinite and thus invalid – the court said it followed "[t]he clear line of Federal Circuit authority dictates that this Court may not re-draft claims to change their ordinary meaning, even if the ordinary meaning produces a nonsensical result." *Teknowledge* (citing *Chef America Inc.*, 358 F.3d at 1374)).

Industry in the 1990's clamored for greater certainty in claim construction as the notice function of patents became of paramount importance. The ultimate reach of the notice function of the mainstream Federal Circuit necessarily is at a price to patentees who do *not* provide fair notice for the invention they disclose but do not properly claim in their patents. The result is a hardball claim construction regime by the mainstream of the Federal Circuit that in its most extreme is perhaps best exemplified in *Chef America.* The patent community has in essence *asked* that the court provide the regime of *Chef America,* and now the flip side of the question is how to adapt patent drafting and prosecution regimes to the realities of such a hardball approach.

§ 20[j] File Record Chart Showing Basis for Claim Elements

It is axiomatic that the patent drafter should leave notes in the applicant's file showing precisely where in the specification there is support for terms used in the claims which are *not* specifically defined in the *Summary of the Invention.* The chances are that by the time of the first action when an issue of claim support is raised in an Examiner's first action, a *different* practitioner will be handling the prosecution than one who drafted the application. Or, memories may fade after two or three years.

In any event, if there is sufficient ambiguity for the Examiner to reject a claim as lacking support, this means that *the Examiner* couldn't figure out the support: Will a fresh practitioner without participation in the drafting process have a better chance of doing so?

Where the practitioner provides an answer to the Examiner that is in fact inconsistent with the drafter's intention and support, this may be a sufficient basis for the Examiner to withdraw the rejection. But, downstream, the careful opponent in a post grant proceeding challenging the patent at the Patent Trial and Appeal Board may be able to see that, in fact, there is now an inconsistency in the prosecution history. This may be a basis to challenge the claim under Section 112(b) as indefinite.

§ 21 Plural Examples for Generic "Upstream" Innovations

A major scientific breakthrough at the "upstream" stage of technology development makes it possible to predict a generic family of products, none of them yet created. The challenge, here is to provide broad generic coverage that will ensnare the "downstream" products that are subsequently made and commercialized.

In a technology that is considered "unpredictable" such as biotechnology the case law has denied generic claims with limited exemplary support on the basis that the limited exemplary support does not establish "possession" of the generic invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc)(Lourie, J.). Multiple examples of the invention help to establish that the inventor actually made representative embodiments of a claimed genus. While there is nothing in the text of 35 USC § 112(a) that compels an inventor to offer *proof* that he has made representative embodiments of the invention, case law interprets the statute as requiring an inventor in an unpredictable art to "establish that the written description conveys to the relevant skilled artisan that 'the inventor[s] actually invented the invention claimed'[.]" *ScriptPro, LLC v. Innovation Associates, Inc.*, 762 F.3d 1355, 1359 (Fed. Cir. 2014)(quoting *Ariad*, 598 F.3d at 1351).

As explained in *Ariad* the "possession" of the invention must be documented in the specification as filed, and not merely shown to be "obvious":

"[I]t is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc*., 541 F.3d 1115, 1122 (Fed.Cir. 2008), or that the specification recite the claimed invention in haec verba, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed.Cir.1997)."

Ariad, 598 F.3d at 1352.

Ariad was based on *Regents of the University of Caliornia v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)(Lourie, J.), which Circuit Judge Rader deemed "a remarkable decision with little, if any, apparent support in the statute of case law[.]" Martin J. Adelman, Randall R. Rader & John R. Thomas, CASES AND MATERIAL ON PATENT LAW § 8.3, p. 431 (3rd ed. 2009).

§ 21[a] "Possession" as part of the "Written Description" Requirement

Even though it may be *obvious* how to make representative examples based upon the inventor's limited actual examples within a broad genus, obviousness is not the test to establish "possession" of a genus in an "unpredictable" art area covered by *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F. 3d 1336 (Fed. Cir. 2010)(en banc)(Lourie, J.).

Ariad was more recently interpreted in *Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc*., 759 F.3d 1285 (Fed. Cir. 2014)(Lourie, J.), which bears close reading by anyone drafting a patent application in the biotechnology field. As explained in *Abbvie Deutschland:*

"'For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.' [*Ariad*, 598 F.3d at 1351] (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). When a patent claims a genus using functional language to define a desired result, 'the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.' Id. at 1349. We have held that 'a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.' Id. at 1350 (*quoting Eli Lilly*, 119 F.3d at 1568-69).

"Here, the claimed invention is a class of fully human antibodies that are defined by their high affinity and neutralizing activity to human IL-12, a known antigen. [The patentee]'s expert conceded that the [ ] patents do not disclose structural features common to the members of the claimed genus. J.A. 7430-31. The question therefore is whether the patents sufficiently otherwise describe representative species to support the entire genus.

"One factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it. That is the case here."

Abbvie Deutschland., 759 F.3d at 1299-1300.

§ 21[b] "Possession" Obviousness not a Substitute for Original Disclosure

The Federal Circuit has reached a conclusion of invalidity in situations of this nature *even where it would have been obvious* how to construct representative examples to show "possession" of the full generic scope of the invention: "[W]e have repeatedly stated that actual 'possession' or reduction to practice outside of the specification is not enough." *Ariad*, 598 F. 3d at 1352.

"[A] description [in the specification] that merely renders the invention obvious does not satisfy the ['possession'] requirement[.]" *Ariad*, 598 F. 3d at 1352 (citing *Lockwood v. American Airlines*, 107 F.3d 1565, 1571-72 (Fed.Cir.1997)).

A panel decision of the Federal Circuit in *Lockwood v. American Airlines*, 107 F.3d 1565 (Fed.Cir.1997). is in *Ariad*, 598 F. 3d at 1352, for the proposition that obvious "possession" outside the specification does not establish the required "possession" requirement in support of the "written description" requirement. As explained in *Lockwood* in the context of determining whether a parent disclosure meets the requirement of "possession" (necessary for priority under what is today 35 USC § 112(a)):

"The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See *Martin v. Mayer*, 823 F.2d 500, 504 (Fed.Cir.1987) (stating that it is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.') (quoting *Jepson v. Coleman*, 314 F.2d 533, 536 (CCPA 1963)). [The patentee] argues that all that is necessary to satisfy the description requirement is to show that one is 'in possession' of the invention. [The patentee] accurately states the test, see *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991), but fails to state how it

is satisfied. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. Id. ('[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.) [ ]. One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba, see *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.Cir.1995) ('[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims ....'), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient."

Lockwood, 107 F.3d at1572.

§ 21[c] Prophetic Exposition of Representative Examples

The Federal Circuit has come down harshly on the patent applicant who may have *known* at the filing date how to make representative examples of an apparently unpredictable genus, *but failed to disclose* the representative examples in the specification as filed.

The answer is that if the representative examples were obvious to the inventor as of the filing date then *why* did the specification fail to *disclose* the obvious representative examples?

The dilemma is thus what approach to take in a situation where generic protection is needed for an "unpredictable" area such as biotechnology where there is a lack of actual representative examples. Here, where construction of the representative examples was obvious to the inventor as of the invention date, the practitioner should include prophetic, present tense discussion showing how the invention is made.

One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. [*Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed.Cir.1991]. ('[T]he applicant must also convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.) [ ]. One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba, see *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.Cir.1995) ('[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims ....'), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient."

Lockwood, 107 F.3d at1572.

§ 21[d] "Prophetic" Example should be drafted in the Present Tense

An example is included in a patent to *teach* how to carry out the invention. Nevertheless, if the example is based upon "prophetic chemistry" where the example does not reflect the results of actual experimentation, the proper treatment of the example is to describe the technology in the *present tense* as in the case of *Atlas Powder Co. v. E.I. du Pont De Nemours & Co*., 750 F.2d 1569 (Fed.Cir.1984).

Use of the past tense for a prophetic example is to be avoided, as seen from this usage playing a major role for holding a patent unenforceable in *Hoffmann-La Roche, Inc. v. Promega Corp*., 323 F.3d 1354 (Fed. Cir. 2003)(Bryson, J.).

The Court in *Hoffmann-La Roche v. Promega* distinguished *Atlas Powder*, noting that "the examples [in *Atlas Powder*] were written in the present tense to conform with the PTO requirements on prophetic examples, and the appellant's claim was that the patentee should have informed the patent examiner that the

examples written in the present tense were prophetic. We held that it was not clear error for the district court to find no materiality or intent to deceive under those circumstances." *Hoffmann-La Roche*, 323 F.3d at 1368 n.1.

The determination of unenforceability in *Hoffmann-La Roche v. Promega* placed heavy emphasis on the use of the past tense to describe a prophetic example:

Example VI is written in the past tense. The inventors state, for example, that a certain quantity of cells "were resuspended in 75 ml of a buffer," that the cells "were lysed in a French press," … after which 300 ml of Tris-EDTA "were added." Each step of the example, over more than two columns of the patent, is described in the same fashion, using the past tense. Indeed, the past tense is used to describe the steps of Example VI on more than 75 occasions. ***

[A] reader of the patent would conclude that the protocol was performed and that the following results were actually achieved: (1) the refined enzyme possessed "single-band purity"; (2) the purified enzyme was free from nuclease activity; (3) the enzyme had a specific activity of approximately 250,000 units/mg; and (4) the specific activity of the enzyme was at least ten times that of the prior art enzyme. ***

[The patentee's witness] admitted that Example VI was never performed.

* * * Misrepresentations by themselves are not enough to render a patent unenforceable; the misrepresentations must be intentional and they must be material to patentability. With regard to the element of intent, [the patentee] has not demonstrated clear error in the district court's finding. The inventors attested that all statements made in the '509 application were true. There was no suggestion by [the patentee] that the use of the past tense in Example VI was an oversight — [the patentee's] Dr. Gelfand admitted he understood that, at least in a scientific publication, the use of the past tense means that an experiment was actually performed. He provided no reasonable explanation as to why a different principle would apply in a patent application. Nor did [the patentee] introduce any other evidence to explain why the past tense was used to describe an experiment that was not performed. Accordingly, the district court did not clearly err in determining that the inventors' use of the past tense in Example VI was knowingly false.

* * *

3. Materiality

* * * Materiality … is not limited to matters reflected in the claims of a patent. See *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.,* 225 F.3d 1315, 1322 (Fed. Cir. 2000). Rather, information is material when there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue. Id. at 1321. Moreover, the information at issue with respect to Example VI consisted of affirmative misrepresentations, not omissions…. This court has held that affirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material. *Rohm & Haas Co. v. Crystal Chem. Co*., 722 F.2d 1556, 1571 (Fed.Cir.1983).

Simplicity in claiming through avoidance of challenging (and unproductive) drafting choices is manifested most notably by the need to avoid "means"-defined elements in claims. Just as important various features that can be included in the specification should also be avoided.

♦ ♦ ♦ ♦ ♦

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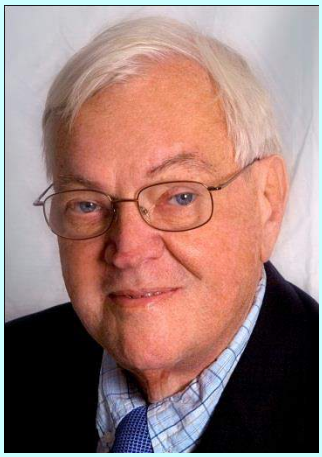

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